IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,

Plaintiff,

vs. No. CJ-2017-816

(1) PURDUE PHARMA, L.P.,
(2) PURDUE PHARMA, INC.,
(3) THE PURDUE FREDERICK COMPANY;
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC.;
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC.; n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC.; f/k/a WATSON PHARMA, INC.;

Defendants.

VIDEOTAPED DEPOSITION OF J&J 3230(C)(5) WITNESS

BRUCE MOSKOVITZ, M.D.

TAKEN ON BEHALF OF THE PLAINTIFFS

ON JANUARY 9, 2019, BEGINNING AT 9:18 A.M.

IN OKLAHOMA CITY, OKLAHOMA

VIDEOTAPED BY: Gabe Pack

REPORTED BY: Jane McConnell, CSR RPR CMR CRR

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(Appearances continued on next page.)

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(Exhibits continued on next page.)

EXHIBITS (Continued)

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STIPULATIONS

It is hereby stipulated and agreed by and between the parties hereto, through their respective attorneys, that the deposition of BRUCE MOSKOVITZ, M.D., may be taken pursuant to subpoena and in accordance with the Oklahoma Discovery Code on January 9, 2018, at the offices of 201 Robert S. Kerr, Oklahoma City, Oklahoma, before Jane McConnell, CSR RPR CMR CRR.

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VIDEOGRAPHER: This is the videotaped deposition of Dr. Bruce Moskovitz in the matter of State of Oklahoma, et al., versus Purdue Pharma, et al.

This deposition is being held at 201 Robert S. Kerr in Oklahoma City, Oklahoma on January 9, 2019. We are on the record at 9:18 a.m.

Will counsel please state your appearances for the record.

MR. PATE: Drew Pate, Nix Patterson, for the State.

MR. LIFLAND: Charles Lifland, O'Melveny & Myers, for Janssen and J&J.

MR. RODRIGUEZ: Esteban Rodriguez, O'Melveny & Myers, for Janssen and J&J.

MR. BOWMAN: Andrew Bowman, Foliart, Huff, Ottaway & Bottom, for Janssen and J&J.

MS. NEWSOME: Jervonne Newsome with Lynn, Pinker, Cox, Hurst for the Purdue defendants.

MR. CURRAN: Jeff Curran, Gable Gotwals, for the Teva defendants.

VIDEOGRAPHER: The court reporter will now swear in the witness.

(Witness sworn.)

* * * * *

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WHEREUPON,

BRUCE MOSKOVITZ, M.D.,

after having been first duly sworn, deposes and says in reply to the questions propounded as follows, to-wit:

DIRECT EXAMINATION

BY MR. PATE:

Q Good morning, Dr. Moskovitz.

A Good morning.

Q Can you please introduce yourself to the jury.

A Yes. I'm Dr. Bruce Moskovitz. Do you want the full name?

Q That's fine.

A Okay.

Q You're a former employee of Johnson & Johnson, correct?

A That's correct.

Q You are being paid to testify today on J&J's behalf, correct?

A That's correct.

Q You have been paid to testify on J&J's behalf a couple of times prior to this in this case, haven't you?

A Yes.

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Q Do you anticipate that you're going to testify again in the future on J&J's behalf in this case?

A Perhaps.

Q How much are you being paid to testify today?

A At a rate of $375 an hour.

Q Today you are testifying on J&J's behalf about certain deposition topics; is that correct?

A Yes.

Q And you understand that the testimony you are going to give today is binding on the J&J defendants in this case, correct?

A I do.

(Exhibit 1 marked for identification.)

Q (BY MR. PATE) I'm going to hand you what I've marked as Exhibit 1 for your deposition. If you will flip to the last two pages, it's my understanding that you are -- have been designated to testify on the topics listed on these two pages with the exception of Topic 18; is that correct?

A Yes. That's my understanding.

Q Are you prepared to do that today?

A I am.

Q Are you prepared to testify on the J&J

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defendants' behalf about information known or reasonably available to those companies about these topics?

A Yes.

Q Now, I've mentioned J&J a couple of times today or the J&J defendants, and I think during your prior depositions we had an understanding that if we refer to Janssen or Johnson & Johnson today, we're referring to all of the J&J defendants in this case unless you tell me otherwise. Can we have that same understanding today?

A Yes.

Q Did you -- what did you do to prepare for this deposition?

A I reviewed a number of documents, some publications, some package inserts, reports to -- periodic reports to the Food and Drug Administration regarding our drugs. I spoke to some folks, reviewed the prior deposition, reviewed some memos and reviewed some of the literature.

Q How much time would you say you spent preparing for this deposition on these topics?

A Well, the topics cross with some of the topics in another deposition. So overall we've had 14, 15 days of preparation, and I've spent some time

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on my own reviewing some of the information, although, I can't really quantify exactly how much that was. It was hours worth of just reading some of the literature. But then in addition to that, as I said, the 14 or 15 days of preparation for the depositions.

Q You referred to a prior deposition that you referred -- that you mentioned to help prepare for today. Was that your prior deposition that you gave in this case in New Jersey?

A Yes.

Q The one where I was asking you the questions?

A Yes.

Q Did you bring -- I think I know the answer to this because there's a stack of boxes over there. I think there's eight bankers boxes. Did you bring some documents with you today to assist you in your testimony?

A Yes.

Q What's in those boxes?

A Backup material relevant to the topics upon which I was designated to testify.

Q Did you select those materials?

A I had a hand in selecting the materials.

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Some of the materials were gathered by the legal group.

Q Do they relate to all of the topics that you're here to testify about?

A There are -- well, there are some topics about which there's really not a whole lot to say. So I would say that they're relevant to the topics upon which I'm prepared to speak.

Q Which topics are there not a whole lot to say?

A Topic 36: "All drugs for opioid use disorder manufactured, owned, contemplated, developed and/or in development by you."

And Topic 37: "All drugs for the treatment of opioid overdose manufactured, owned, contemplated, developed or in development."

Q So you said there's not much to say --

A Right.

Q -- on those topics?

A I can answer your questions, but there's not much to say about those.

Q So you don't have documents with you related to those?

A Because there aren't any drugs that we developed in those two cases.

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Q There are no drugs for either of those two cases?

A No.

Q We'll come back to that.

So the eight boxes you have over there, those relate to the remaining topics that you are designated to testify about today and tomorrow and the next day; is that right?

A Yes. That's correct.

Q Do those boxes contain all of J&J's research related to the risks and benefits of opioids?

A They do to the best of my knowledge. It's clearly the data that we were aware of. There may be additional data out there that we weren't aware of, but to the best of my knowledge they do.

Q Do they contain all of the scientific support that J&J is aware of for any of its marketing statements about opioids?

A Yes, to the best of my knowledge they do.

Q Do those boxes contain all of the scientific support that J&J is aware of for any statements that it's made about pseudoaddiction?

A Yes. Again, to the best of my knowledge, they do. I mean, again, I want to be clear, there

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may be other articles out there that we're not aware of, but certainly these are the articles that J&J is aware of.

Q If it's not in one of those boxes, you're not aware of it?

A That's correct.

Q If it's not in one of those boxes, you're not aware of it and haven't identified it as a piece of support for the concept of, let's say, pseudoaddiction; is that right?

A That's correct.

Q And if it's not in one of those boxes, you're not aware of it and J&J hasn't identified it as support for any of its marketing statements about the risks or benefits of opioids; is that right?

MR. LIFLAND: I'm going to object to the form of the question.

A That's my understanding, yes.

Q (BY MR. PATE) Is the Porter and Jick letter in there?

A I believe it is.

Q Are those boxes organized in any -- in any fashion?

A Yes. There are major topics that I've been asked to testify on, and I think based upon the

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topic, I have some materials with me at a very high level that I can address.

And then if we need to take a look at some of the information in more detail, I have access to it in those boxes.

Q The high level materials you referred to, are those the documents you have in front of you?

A Yes, they are.

Q Can you describe those documents for me.

A I have a high level timeline over some of the key events relative to Duragesic and Nucynta.

I have documents that speak to the information relative to the topic -- to the topics relative to pseudoaddiction, relative to our websites, relative to abuse, misuse, dependence, addiction, the opioids that we manufactured, owned and/or developed, our risk management plans to look at issues of abuse, misuse, diversion, use of our drugs, safety surveillance, studies related to safety, efficacy of Duragesic and tapentadol, Nucynta, and additional information supporting certain categories of statements.

Q Do you have copies of those documents that you're looking at right now?

MR. RODRIGUEZ: We do, yeah. Here's a

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copy.

MR. PATE: Thank you.

(Exhibit 2 marked for identification.)

Q (BY MR. PATE) You've been handed a document marked as Exhibit 2. Have you ever seen that?

A I have not.

MR. LIFLAND: Hold on a second.

Q (BY MR. PATE) Have you ever seen that, sir?

A Let me look through it, but I don't recall that I have. No, I have not.

Q Exhibit 2 are excerpts of a document that was produced to us and only printed out --

MR. LIFLAND: Can you clarify who produced it.

MR. PATE: I think it's been produced by more than one, more than one party in the case. I'm not sure who produced this particular version of it with this Bates number.

MR. LIFLAND: I guess my question is was it produced by Janssen and Janssen or John -- or Janssen or Johnson & Johnson?

MR. PATE: No. As far as we know, Janssen hasn't produced this yet.

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MR. LIFLAND: That's my only question.

Q (BY MR. PATE) Do you know what the Pain Care Forum is, Dr. Moskovitz?

A No.

Q You never heard of the Pain Care Forum?

A I -- no.

Q Were you aware that Johnson & Johnson was a member of the Pain Care Forum?

A No.

Q This document is a copy of a presentation that was given in June 2013, excuse me, June 13, 2006, supported by the American Pain Foundation and the Pain Care Forum.

If you will turn to the page that ends in 2059. There's a heading here for "Prevalence Fast Facts." Do you see that?

A I do.

Q The third bullet down reads, "Although pain has been studied extensively by medical researchers and treatments exist to relieve or ease pain, the reality is that most pain goes untreated, undertreated or improperly treated."

Did you see that?

A I do.

Q Are you aware of any scientific support

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that most pain goes untreated?
A Throughout the course of my tenure with Johnson & Johnson, there were a lot of articles that address this. I actually think that we spoke of one article at the last deposition where we looked at treatment of pain relative to how severe it was and what was used.
So there are publications that address this, yes.
Q The article you just specifically mentioned, let's talk about that real quick. That is your article that you helped author, correct?
A Yes.
Q The one where hydrocodone was placed in the weak opioid category?
A That's correct.
Q Other than that article, what other scientific support is there for this statement that most pain goes untreated?
A I would have to refer back to many of the articles about pain, many of which reference that. I can't point to a specific one at the moment, but it's a concept that even was discussed at FDA advisory meetings that there is the concept that pain is undertreated and a lot of patients aren't

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treated adequately.
Q Other than the article that you helped author, that we already mentioned, is there a specific article that you can point me to today that is Janssen's scientific support for the idea that pain -- most pain goes untreated?
A Again, I'd have to go back to the literature. I know that in many of the articles that talk about pain treatment, they reference the incidence and prevalence of pain and state facts relative to what you just stated, that many patients are undertreated or don't get treatment, but I can't point to a specific one at the moment. In a review I'm sure I can bring that to you.
Q Let me ask you this. As far as you know, J&J itself has never conducted a study to determine whether or not most pain goes untreated; is that correct?
A No. That's correct, that we have not conducted a study whether most pain goes untreated.
Q You have not conducted a study to determine the percentage of pain that goes untreated; is that right?
A No.
Q No, you haven't done the study?

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A No, we haven't done a study.
Q In this same sentence it says, "Most pain also goes undertreated."
Are your answers the same for that?
A Yes.
Q You don't have -- J&J hasn't conducted a study to determine how much pain goes undertreated, correct?
A Well, again, relative to even the publication that we spoke of at the last deposition that made a point that there is pain that goes undertreated, I don't know that I would quantify it as most, some, some degree, but there is pain that goes undertreated.
Q But you haven't done a study to confirm or determine whether most pain goes undertreated, correct?
A That's correct.
Q And you're not aware of any studies sitting here today that show that most pain goes undertreated, correct?
A Again, I'd have to refer back to the literature, but I'm not aware of a specific study that puts it in those terms, most pain goes undertreated.

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Q The next statement says, "Most pain also goes or improperly treated." Do you see that?
A Yes.
Q J&J has never conducted a study to demonstrate that most pain is improperly treated, correct?
A I'm not aware of any.
Q You are not aware of any study at all showing that most pain is improperly treated, correct?
A Publications but not a study and certainly not a study that was done by J&J that I'm aware of.
Q Even if there's one not done by J&J, I'm asking, are you aware of any study/publication that shows that most pain is improperly treated?
A I'm not.
MR. LIFLAND: Object to the form of the question.
Q (BY MR. PATE) The next statement or the next bullet on the same page, it says, "Chronic pain is a major cause of absenteeism and unemployment. In fact, pain results in more than -- or more that 50 million lost work days each year and costs the United States economy an estimated $100 billion in lost productivity and health care expenses."

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Do you see that?
A I do.
Q What is the scientific support for that statement?
MR. LIFLAND: Object to the form of the question.
A I know that there were studies done that looked at the impact of pain on absenteeism. Again, I'd have to refer back to the literature.
That was a theme that was generally understood in the pain community that the impact of pain was not just a matter of a patient experiencing pain, but that it kept him or her from functioning effectively which, in fact, was why there's a focus on functionality as well as pain relief. But I'd have to go back to the literature to speak about the studies that support that.
Q (BY MR. PATE) You say you'd have to go back to the literature, what literature are you referring to?
A Some of the articles that are referenced in finding relief, the references that we used for the website.
Just by virtue of the title, I see one over here that speaks to underutilization of opioid

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analgesics in elderly patients with chronic pain.
Q What are you referring to?
A I'm referring to a reference that was used in the prescriberesponsibly.com website, No. 17.
Q That article you are saying is scientific support for this statement that chronic pain is a major cause of absenteeism and unemployment --
A No. Finish your sentence. I'm sorry.
Q The article you just referenced, "Underutilization of opioid analgesics in elderly patients," you have it on Page 1 of your references for prescriberesponsibly.com is Tab No. 17; is that correct?
A That's correct, yes.
Q You cited that as support for the statement that "chronic pain is a major cause of absenteeism and unemployment. Pain results in more than 50 million lost work days each year. It costs the economy an estimated $100 billion."
Is that correct?
A I misspoke in that it relates more to the point we just spoke about previously about pain being undertreated. So it doesn't address the specific question you just asked about the impact.
Q We'll come back to that study then, but

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what -- let's go back it my original question.
What scientific support, if any, can you point to for the statement that "pain results in more than 50 million lost work days each year and costs the United States economy an estimated $100 billion in lost productivity and health care expenses"?
MR. LIFLAND: Object to the form of the question.
A Yes. Offhand, I can't speak to any. I'm accustomed when I see these things to having referenced material and I would go to the references. There are no references provided with this.
So offhand I can't answer that. I'm not aware of any just by virtue of the statement.
Q (BY MR. PATE) Is it generally appropriate if you're going to make claims about opioid products and things like that that you would provide references for the claims you're making?
MR. LIFLAND: Object to the form of the question.
A Yes. Generally we would.
Q (BY MR. PATE) You would not support, you personally, because you dealt with stuff like this

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as part of your job at J&J, right?
A That's correct.
Q You personally wouldn't have supported the idea of just throwing out statements and numbers without having and citing references for them, correct?
MR. LIFLAND: Object to the form of the question.
A Correct. If we are making a statement under our heading that would be a reference that would support that statement, in most instances you would see the reference there, and then you would be able to go to it, but in this instance I don't see a reference.
Again, it's not to say that there isn't. I'm not aware of any, and there's no reference provided over here.
Q (BY MR. PATE) If you'll turn next to the page that ends in 2103. There's a bullet in the middle of the page that reads, "Health professionals and the public are unaware that, one, physical dependence on a medication is not the same as addiction; two, appropriate use of opioid medications like oxycodone is safe and effective and unlikely to cause addiction in people who are under

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the care of a doctor and who have no history of substance abuse; and, three, opioid medications are sometimes the only effective treatment for some types of pain."

Did I read that correctly?

A Yes.

Q What's the scientific support for the statement that "appropriate use of opioid medications like oxycodone is safe and effective and unlikely to cause addiction"?

MR. LIFLAND: Object to the form of the question.

A Let me start off by saying there are no references provided in the materials that you gave me, but I'm certainly aware that there are studies that looked at the incidence of addiction in individuals who are treated with opioids, and there are a number of articles that address that.

Q (BY MR. PATE) There are a number of articles that show that opioid medications like oxycodone are unlikely to cause addiction?

MR. LIFLAND: Object to the form of the question.

A That the rate of addiction in patients treated with those medications is relatively low.

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Q (BY MR. PATE) What's "relatively low" mean?

A Well, in the papers that I reviewed in the range of say 2 to 5 percent. Now, again, that depends upon the past history. So patients with a prior history of addictive behaviors or use of other substances may have a higher incidence. But, in general, for patients who don't come with that history or are managed properly, the incidence is low.

Q When you said low, what do you mean by low?

A In the range of what I quoted to you, 2 to 5 percent.

Q 2 to 5 percent is low to you?

MR. LIFLAND: Object to the form of the question.

A One could argue about relative terms like low, medium, high, yes. When we speak about adverse events, those are considered to be low.

Q (BY MR. PATE) You said there are a number of articles that address that, that support what you just said, that there's a low risk of addiction for opioid medication; is that right?

A That's correct.

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MR. LIFLAND: Object to the form of the question.

Q (BY MR. PATE) What are those articles?

A There's an article by Fleming, there's an article by Banta-Green, there's an article by Boscarino, there's an article by Fishbain.

Q Are you reading that off of the document you have in front of you or are you recalling that?

A Well, we've previously spoken about these articles at other depositions. So I'm aware of the articles. So at the moment I'm reading it off of here.

Q Those are the same articles that we talked about at your last deposition, you and I?

A Yes.

Q Right now you're reading from what?

A A summary of some of the articles that support various statements.

Q Is it in this one? Can you identify what you're looking at for me.

A It starts with, "Selected studies, research and analysis of safety and efficacy of Duragesic and Nucynta."

Q What page are you on?

A Page 16.

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Q Can I see the one that you've got in front of you real quick. I'd like to mark that. Thank you.

(Exhibit 3 marked for identification.)

Q (BY MR. PATE) I've marked the document that -- one of the documents that you brought with you as Exhibit 3 so that we can talk about it.

A Okay.

Q Can you just describe what Exhibit 3 is for me real quick.

A These are references, information that we have that addresses some of the topics that I've been asked to speak about today. In this instance it would be "Selected studies, research and analysis of safety and efficacy of Duragesic and Nucynta."

If I may, in addition, I think we've also spoken about that we have internal reports that address iatrogenic addiction, a report that we did on Duragesic internally.

Well, this wasn't related to addiction. So I'm not going to bring it up.

Q What were you just thinking of?

A We -- well, so let me take a step back.

In all of our studies as part of adverse event reporting, addiction may be an adverse event

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that's reported. So we collect the incidences of adverse event.

But I was specifically referring to withdrawal symptoms that we measured specifically in one of our studies.

Q Earlier when I asked you what are the articles that support the concept that opioid medications like oxycodone are safe and effective and unlikely to cause addiction in people not -- who are under the care of a doctor, and you listed the four articles, correct?

A That's correct.

Q You said you were -- at the time you were reading them off of somewhere in Exhibit 3. Can you point me to that page.

A That's Page 16.

Q Let's just go down the list. So these are the articles. Before we do that, these are the articles that you're aware of and that you would rely on for this statement that we see in Exhibit 2 that opioid medications like oxycodone are safe and effective and unlikely to cause addiction in people under the care of a doctor, correct?

A Yes.

Q The first study, the Fleming study, was

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published in 2007, correct?

A That's correct.

Q Where was that published?

A In Journal of Pain.

Q Was it peer reviewed?

A Yes. That's my understanding that the Journal of Pain peer reviews the articles. That's my understanding. So I don't want to speak out of turn for them, but it's my understanding that the Journal of Pain is a highly regarded journal and that they peer review all the articles.

Q The authors are listed right here on Page 16, correct?

A That's correct.

Q Who paid for this study?

A I have no idea.

Q Did J&J contribute to it?

A I don't believe so. I have no information that we did.

Q Do you know whether or not a different pharmaceutical contributed to the study?

A I have no idea.

Q Do you know what the criteria were for this study?

A I'd have to review the study.

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Q Do you have it with you?

A We have access to it, yes. I'm sorry. I don't understand what you mean by "criteria."

Q How was it done? How was the study done?

A That would be described in the methodology section.

Q Did you contribute to the study in any way?

A No.

Q Did J&J contribute to the study in any way?

A I don't believe so.

Q Did it review it before it was published?

A I don't believe so.

Q Did you make any edits to it?

A No.

Q Any other pharmaceutical companies, as far as you're aware, have any role in the publication of that study?

A Not as far as I'm aware.

Q Do you know how the patients or doctors were selected in that study?

A I'd have to review the methodology.

Q The second article that you pointed to is the Banta-Green article listed next on this page,

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correct?

A Yes.

Q That's a 2009 publication, correct?

A That's correct.

Q Where was it published?

A Drug and Alcohol Dependence.

Q Was it peer reviewed?

A I can't -- I don't know the publication strategy for this journal article.

Q But you rely on it as support, correct?

A As part of a number of articles, yes, especially when they describe the methodology so we understand how they got to their results.

Q Did J&J fund this study?

A Not to my knowledge.

Q Did J&J contribute to it?

A Not to my knowledge.

Q Did it review it before it was published?

A No.

Q Make any edits to it?

A No.

Q Make any suggestions on it?

A No.

Q Any other pharmaceutical company do those things?

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A Not to my knowledge.
Q Do you know whether or not J&J has ever provided funding or honoraria or anything of value to any of the authors to the Banta-Green study?
A I don't know.
Q Do you recognize any of those people as key opinion leaders?
A No.
Q Or as paid speakers for Janssen?
A No.
Q What about back on the Fleming study, have any of those people ever been key opinion leaders of J&J?
A Not to my knowledge.
Q Or paid speakers?
A Not to my knowledge.
Q The next article that you cited as support for the statement in Exhibit 2 about addiction is the Boscarino study, correct?
A Yes.
Q That's a 2010 publication, correct?
A Yes.
Q And it was published where?
A Addiction.
Q Was it peer reviewed?

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A Again, I don't know their requirements.
Q Did J&J contribute to it?
A Not to my knowledge.
Q Did it provide any support for it?
A Not to my knowledge.
Q Did it review it before it was published?
A No.
Q Did it make any edits to it?
A No.
Q Any other pharmaceutical company, as far as you know, aware of the publication of this study?
A Not to my knowledge.
Q Has J&J provided any funding or grants, anything of value to the authors of this study?
A Not to my knowledge. I'm not familiar with them.
Q You don't recognize any of them as key opinion leaders or paid speakers for J&J?
A I don't.
Q The last article that you cited as support for the statement in Exhibit 2 about addiction is the Fishbain article, correct?
A Yes.
Q Listed here on Page 16, correct?
A Yes.

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Q That was published in 2008, correct?
A Yes.
Q And the authors are listed, all the authors listed here on the page?
A I'd have to go back to the article. There may be additional authors. I don't know. Sometimes they'll cut off the number of authors. So I can't say that this is a complete list.
Q Where was it published?
A Pain Medicine.
Q Was it peer reviewed?
A I believe Pain Medicine is a peer-reviewed journal.
Q Do you know who funded this study?
A I don't.
Q Did J&J provide any funding for it?
A Not to my knowledge.
Q Provide any support to it?
A Not to my knowledge.
Q Did it review it before it was published?
A No.
Q Are you aware of any other pharmaceutical company that did?
A No.
Q You're citing studies from 2007, 2008,

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2009 and 2010 as support for the statement that I read to you from Exhibit 2, correct?
A Yes.
Q The one about opioid medications like oxycodone are safe and effective and unlikely to cause addiction in people who are under the care of a doctor, right?
A And have no history of substance abuse.
Q And who have no history of substance abuse.
A That's correct.
Q You're aware that the document in Exhibit 2 is a 2006 publication, correct?
A I'm sorry.
Q This is from 2006.
A Okay.
Q Are you aware of that?
A Yes.
Q So the articles that you pointed to, none of those would have existed or have been published in 2006, correct?
A That's correct.
Q Anyone who wrote Exhibit 2 wouldn't have known or been able to rely on anything in the articles you just pointed to in order to support the

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statement they made in Exhibit 2, correct?
A Not for 2006, that's correct.
Q You agree that people, pharmaceutical companies, shouldn't make statements about the addiction risk of a drug like oxycodone without having scientific support for it, correct?
A I believe that there should be scientific support that underpins a scientific statement.
Q J&J doesn't make any oxycodone products, does it?
A No.
Q J&J has never made any oxycodone products, has it?
A Well, we explored tamper-resistant formulations of oxycodone. We never developed them. We never marketed them.
Q You never put an oxycodone product on the market?
A That's correct.
Q So as far as -- I assume then J&J has never done its own study specific to oxycodone to determine what the rate of addiction is for oxycodone in people who are under the care of their -- or taking it under the care of a doctor; is that right?

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A Only with respect to adverse event reporting where oxycodone was a comparative drug.
Q You've never taken oxycodone and said let's figure out how addictive oxycodone is for people who are taking it under the care of a doctor, correct?
A That's correct.
Q Are you aware of any study that does that?
A Specific to oxycodone you're asking?
Q Yes.
A I'm not aware.
Q Will you turn to the page ending in 2119. The bullet that is second from the bottom reads, "In most communities it is difficult for pain patients to find physicians willing to prescribe opioid medicines for pain."
Did I read that correctly?
A Yes.
Q Do you recall this document was published in 2006, right?
A Yes.
Q What is the support for the statement that in most communities it is difficult for pain patients to find a physician willing to prescribe an opioid for their pain in 2006?

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A I don't know.
Q You're not aware of any?
A I'm not aware of any and there's no reference given.
Q And J&J, as far as you know, has never conducted a study to demonstrate whether or not pain patients have trouble finding physicians to prescribe them opioids?
A No. We did not.
(Exhibit 4 marked for identification.)
Q (BY MR. PATE) I've handed you a document marked as Exhibit 4. Do you recognize that document?
A Yes.
Q What's Exhibit 4?
A It's a website. No, this was a monograph, I believe, that was developed with a DVD for information about pain and pain management for physicians and patients.
Q What we see in Exhibit 4 was provided to both doctors and their patients, correct?
A Through their physicians, yes.
Q This was part of a national marketing campaign, correct?
A I don't recall the scope of it, but I

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believe so.
Q It wasn't exclusive to any particular area of the country?
A Of the country, I'm not aware of that, no.
Q In the bottom right we see a reference that this publication was sponsored by PriCara?
A PriCara.
Q PriCara?
A Yes.
Q A division of Ortho-McNeil-Janssen Pharmaceuticals, correct?
A Correct.
Q That's a Johnson & Johnson entity, correct?
A That was the name of the pharmaceutical company at the time, yes.
Q J&J sponsored what we see in Exhibit 4, correct?
MR. LIFLAND: Object to the form of the question.
A Yes.
Q (BY MR. PATE) This was published in 2009, correct?
A Yes.
Q If you'll turn to Page 17. Are you on

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Page 17, sir?
A I am.
Q There's a box labeled "opioid myths." Do you see that?
A I do.
Q The first myth listed is that "opioid medications are always addictive."
Then underneath that it says, "Fact: Many studies show that opioids are rarely addictive when used properly for the management of chronic pain." Correct?
A I do. Yes.
Q And the word "rarely" is emphasized and italicized in that sentence, correct?
A Yes.
Q What is the scientific support for the statement that "many studies show opioids are rarely addictive when used properly for the management of chronic pain"?
A In addition to the studies that we just discussed, there are a number of references that support the statements in the Finding Relief. I'd have to review them to see which ones specifically address the fact that's mentioned over here.
Q You're holding something in front of you.

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What is that you're holding there?
A References relative to the Finding Relief.
Q Let's mark that.
(Exhibit 5 marked for identification.)
Q (BY MR. PATE) I've marked the document, one of the documents you brought with you as Exhibit 5. Can you just identify what Exhibit 5 is.
A These are references that were used in support of statements made in the Finding Relief monograph.
Q Exhibit 4 is the Finding Relief monograph, correct?
A Yes.
Q And you came today with the table that we see in Exhibit 5 which is all of the scientific support for the statements made in Finding Relief?
A Yes.
Q There are it looks like 25 or so articles listed. Which ones -- I'm sorry.
A Yes. I wasn't counting them down. Yeah.
Q Which ones -- however many you have listed here, which ones relate or show that opioids are rarely addictive when used properly for the management of chronic pain?
A I would have to go back and review the

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individual articles, but just by title they do cite the Porter and Jick letter.
Q Where did you get the list that's in Exhibit 5?
A This was provided to me by counsel.
Q All right. The article that you pointed to is as support for the statement, "Many studies show that opioids are rarely addictive when used properly for the management of chronic pain."
The article you point to is the Porter and Jick letter on Page 2; is that right?
A By title. As I said, I'd have to review other articles to see where in the article they address the incidence of addiction.
Q Let me ask my question again. I just need the record to be clear.
I asked you which articles support this statement, "Many studies show..." So far the one you've pointed to on your list is the Porter and Jick letter, right?
A Yes, and the articles that we spoke about, the Fishbain, Boscarino and other articles, but they're not listed over here.
Q Those are not listed in Exhibit 5?
A That's correct.

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Q Are there any other articles in this list on Exhibit 5 that support this statement about "many studies show opioids are rarely addictive"?
A There may be. I'd have to go back to the individual articles and see whether they support that.
Q Well, I'm guessing that's why you brought eight boxes with you. So I need an answer to the question. So if you need to look at the boxes or whatever you need to do, feel free, but I need to know which studies J&J says support this statement.
A Okay.
If I may for a moment, just because we spoke about it, there are some statements also that address some of the concerns you raised earlier about the incidence and the inadequate treatment.
Q The incidence and inadequate treatment, you're talking about the statements from Exhibit 2 about how many or whether or not most pain goes untreated, undertreated or improperly treated?
A Yes.
Q Do you think you've identified something that supports that?
A I do just in looking for the other.
Q What is it?

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A This is a -- it's a journal article in the Clinical Journal of Pain titled, "The Use of Opioids for the Treatment of Chronic Pain, a Consensus Statement from the American Academy of Pain Medicine and the American Pain Society."
Q When was it published?
A 1997.
Q Who was the author?
A This is a consensus statement. They give a listing of the committee members.
Q What tab are you looking at in your binder?
A I'm looking at Tab 5.
Q From the Clinical Journal of Pain?
A Yes.
Q Do you know how much money J&J has provided to the American Academy of Pain Medicine?
A I do not.
Q You know that they have provided money to that organization, correct?
A I believe we have supported a number of their programs.
Q And J&J also supports the American Pain Society and has provided money to them as well, correct?

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A Yes.
Q Do you know what the parameters were of this study?
A I don't. Again, could you define what you mean by "parameters."
Q How did this study determine that most pain goes untreated?
A I don't know.
Q How did this study determine that most pain goes undertreated?
A I don't know.
Q How did this study determine that most pain is improperly treated?
A I don't know.
Q But you're stating that this study does support those ideas?
A They don't provide references. I know the American Academy of Pain Medicine is a highly regarded society, and I would venture that they have appropriate backup for these statements.
Q But you don't know?
A I don't know. That's correct.
Q And the study itself doesn't provide any?
A That's correct.
Q If you'll continue trying to identify for me any other articles that support the --

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A Uh-huh.
Q -- the statement from Finding Relief that many studies show that opioids are rarely addictive when used properly for the management of chronic pain other than the Porter and Jick letter.
A Again, if I find material that references what we had spoken about previously, do you want me to bring it up?
Q I would like to know that. I would suggest for purposes of our record that you stick with trying to answer this question. I'm happy to give you a pen if you want to make some notes about things you want to come back to. If you think --
A Perhaps a sticky. Thank you.
Q You're welcome.
A Can I?
Q (Nods affirmatively.)
A Do you want me to bring it up as I come to them?
Q Sure.
A Okay. There's a citation in Tab 6.
Q "Principles and Practice of Medicine, Warfield."
A "Pain: Current Understanding of Assessment, Management and Treatment."

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I'm on Page 17. "Most experts agree that patients who undergo prolonged opioid therapy usually develop physical tolerance..." I'm sorry. I'll try to slow down for you. "...but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although, the actual risk of addiction is unknown, it is thought to be quite low. A recent study of opioid analgesic use revealed low and stable abuse of opioids between 1990 and 1996."
Do you want me to go to the references that are cited here?
Q You're reading from Page 17?
A I'm reading from Page 17, Section B, "Etiology, Issues and Concerns."
Q The article doesn't cite any support for the statement that "In general, patients in pain do not become addicted to opioids." Correct?
A I'm sorry, I'd have to -- so to my knowledge, it's saying that if the rate of addiction is low, in general you're not going to become addicted.
Q You're saying because --
A So I'm saying the statement "most experts

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agree that patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders" would support that statement.

Q I see. Okay. What's the basis for that statement?

A Let me go to 152. Citation 152 is the American Society of Addictive Medicine definitions related to the use of opioids for the treatment of pain consensus document from the American Academy of Pain Medicine, American Pain Society and American Society of Addictive (sic) Medicine, February 2001, and it's a website that can be accessed, and they give the link.

Q The actual document that's being cited is something published by the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine, correct?

A Correct.

Q You're aware that the American Academy of Pain Medicine and the American Pain Society are two organizations that J&J has contributed significant money to, correct?

MR. LIFLAND: Object to the form of the question.

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A I can't answer significant. I don't know what significant is. We support their programs.

Q (BY MR. PATE) So that's one article that they cite for "Most experts agree patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders." Correct?

A Correct.

Q And the article goes on to state, "In general, patients in pain do not become addicted to opioids. Although, the actual risk of addiction is unknown. It is thought to be quite low." Correct?

A Correct.

Q This articles states, "The actual risk of addiction is unknown." Correct?

A Correct.

Q Do you agree with that?

A Based upon all the information I've seen for patients without -- who are properly selected, properly monitored, properly followed up and properly educated, I believe that to be so, yes.

Q So far you've cited the Porter and Jick letter and this article, "Pain: Current Understanding of Assessment, Management and Treatments" for support for the statement in the

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Finding Relief about rare addiction.

Are there any other articles?

A Again, we've spoken about the Fleming article, the Boscarino article, the other articles previously. I don't see them listed in here, but they support the statement as well.

Q So those four plus you've pointed to two more.

A (Witness nods affirmatively.)

Q Are there any others?

A There is a statement in that same section, Page 53, at the very -- the very bottom of the first column. "Although, not usually encountered in patients without a history of preceding drug abuse, the administration of some drugs may cause addiction."

So not usually seen in patients without a prior history of addiction, there is no reference.

Q You as a doctor would probably like to see a reference for that, right?

A It's preferable, absolutely.

Q Outside of this study, so you've identified this study or this article, you identified the Porter letter, the Fleming, Boscarino, and the two others that we previously

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discussed.

A Correct.

Q What other articles, if any, in this binder are you aware of that support the rarely addictive statement in Finding Relief?

A There is a citation in here for the Porter and Jick just as an aside.

There is another paper I think we've mentioned in the past also among burn patients that has been cited as well. If you want, I'll read you the citation.

Q Sure.

A That's Perry and Heidrich, "Management of Pain During Debridement: A Survey of US Pain Units."

They indicate, "A national survey of over 10,000 burn patients without prior histories of drug abuse who received opioids for extended periods revealed no cases of addiction. Only three of 2,369 chronic headache patients, most of whom had access to opioids, abused the analgesics."

That's a different reference, and that was Medina and Diamond, Drug Dependency in Patients with Chronic Headache, and that's in the journal, Headache.

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Q That's different than the burn study?
A That's different than the burn study, yes. Do you want the -- I think I gave you the references for both.
Q The burn study is Perry, the Perry study?
A 64, the burn study is Perry, that's correct.
Q Please continue.
A Okay. There's a citation here with Porter and Jick.
There is -- I'll read you the sentence here. "Senay," who's the physician being quoted. "Senay examined 1,900 patients enrolled in an Illinois drug treatment program and convinced himself that three began their careers with a legitimate medical exposure."
Q What are you reading from?
A I'm reading -- this is Tab A.
Q 16A?
A Yes. Tab A, Page 170, at the bottom there's the Porter and Jick reference and then that goes on, the very last sentence at the bottom there.
On Tab B, the Use of Opioids for the Treatment of Chronic Pain, this is the consensus statement from the American Academy of Pain

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Medicine, the American Pain Society on Page 6 at the bottom, no reference, but in the section, Section 4, "Current information and experience suggests that many commonly-held assumptions need modification."
It goes on to speak about addiction, and there's a statement on Page 7, five lines down, "Studies indicate that the de novo development of addiction when opioids are used for the relief of pain is low." There's no reference there.
Tab E is the Porter and Jick letter.
Tab F is the Perry letter. I'm sorry, the Perry article on debridement in a burn unit.
Q I just want to clarify. Your document, Exhibit 5, that is the reference sheet for all of these, it lists -- I think it's one off on its references. It lists the Porter and Jick letter as 16D. I just want to clarify that what you're pointing to are the actual articles in the binder. 16E is Porter and 16E --
A 16E is the Porter and Jick letter.
Q Right.
A Yes. And 16F is the Perry article. 16G is the article on chronic headache, the Medina and Diamond article.
MR. LIFLAND: While he's looking, maybe we

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can clarify this because I think you did -- it looks like what's in the notebook as 16B, which he referred to previously as the consensus statement, is not included in the, I'm sure inadvertently, in the index. So that's where the lettering goes off.
MR. PATE: Okay.
MR. LIFLAND: So B should be the consensus statement, and then what's labeled as B should be C, what's labeled as C should be D and so on.
MR. PATE: Thank you.
A As an aside, there's a reference to hydrocodone being a weak opioid, too.
Q (BY MR. PATE) What are you looking at?
A I'm looking at, "Uses and misuse" -- this is under Tab K, "Uses and misuses of medication in the management of chronic non-cancer pain."
Q Where are you reading?
A An article by Hare and Lipman. I'm looking at Page 584, the second column, second paragraph. "The weak opioids include propoxyphene, codeine, oxycodone and hydrocodone.
Q Let's talk about that for a minute. You would never consider oxycodone to be a weak opioid, would you?
A I would not.

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Q And I think that we talked a lot about whether or not hydrocodone was a weak opioid at your last deposition, and we agree that hydrocodone by itself is not a weak opioid, correct?
A Hydrocodone as a single agent is not a weak opioid; although, we found varying potency equivalents with morphine most of which considered to be at a one-to-one potency.
But we also spoke about the limitations in using hydrocodone because at the time it could only be given with acetaminophen.
Q That's hydrocodone. Oxycodone is actually more powerful and more potent than morphine, correct?
A I agree. I'm sorry. These things come up in the review. Okay. That's what I see in the binder over here.
Q I'd like to go back to Tab B, the consensus statement that you referred to.
A Okay.
Q It lists several committee members who helped prepare this statement, on the bottom left of the first page. Do you see that?
A I do.
Q David Haddox is the first person listed,

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isn't he?
A Yes.
Q David Haddox works for Purdue Pharmaceuticals, doesn't he?
A I don't know his current employment, but he did, and I don't know the dates.
Q The next person listed is David Joranson, right?
A Yes.
Q He's associated with a group known as PPSG, the Pain & Policy Studies Group from Wisconsin, isn't he?
A I don't know.
Q Then another consultant that is listed here is a Dr. Russell Portenoy, correct?
A Yes.
Q Dr. Portenoy is someone we spoke about at your last deposition, right?
A Correct.
Q He was believed and treated by J&J as a key opinion leader for a number of years in the opioid treatment area, right?
A He was considered to be a key opinion leader, yes.
Q He was someone you provided money to?

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MR. LIFLAND: Object to the form of the question.
A I don't -- I don't believe from medical affairs because I don't believe he did a study. From medical affairs we would have provided money if they were doing a clinical -- a study for us. I'd have to go back to the funding. So I don't know from medical affairs that we ever provided funds to him.
Q (BY MR. PATE) You're aware that Dr. Portenoy has done a lot of work for a lot of opioid manufacturers, correct?
A I would clarify "work" for him. He's certainly regarded as a key opinion leader, and his knowledge is sought when we are looking for advice on various aspects of pain management and treatment, and I would assume without knowledge that that's true for other companies as well.
Q The consensus statement is provided here by a group called the American Academy of Pain Medicine, right?
A Yes.
Q And the American Pain Society, right?
A Yes.
Q You're aware the American Pain Society is

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a group that trademarked the phrase "pain is the fifth vital sign." Is that right?
A I'm aware of the phrase. I didn't know that they trademarked it.
Q You're aware that both of these groups accept large amounts of money from pharmaceutical companies like J&J, correct?
MR. LIFLAND: Object to the form of the question.
A I'm aware that we fund their programs. Again, the use of terms like "large" you'd have to specify.
Q (BY MR. PATE) Are you aware that members of a Senate inquiry have investigated the ties between these groups and companies like J&J, the financial ties?
MR. LIFLAND: Object to the form of the question.
A I wasn't aware of that.
Q (BY MR. PATE) The specific statement that you pointed to to support the claim that studies show opioids are rarely addictive, I believe you pointed to Page 7, top left, where it says, "Studies indicate that the de novo development of addiction when opioids are used for the relief of pain is

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low." Correct?
A (Witness nods affirmatively.)
Q They don't provide any support for that statement in this article, do they?
A Correct. There's no reference in this article.
Q This was published in 1997; is that right?
A Correct.
Q Are you aware of any studies that existed in 1997 that would have supported that statement?
A What was the year of the Porter and Jick letter?
Q 1980.
A Okay. So that would have been in the Headache. I'd have to go back to the -- some of those studies were before 1997. I don't recall which ones were.
Q The Porter and Jick study is the first one that comes to mind for you?
A Only because I know that was one of the very earliest citations.
Q As scientific support for this statement?
A As a report of observations on a large group of individuals that Porter and Jick followed. It's a letter to the editor. It's a report of an

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observation.
Q Well, now I'm not sure I understand your answer. So let me ask again.
Is the Porter and Jick study something you would call scientific support? Is it science?
A I can't readily answer that. It's an observation on what they saw. Science is the gamut of formal controlled clinical trials where the methodology is provided to observations. Observation provides information as well. To the extent it provides information, I would classify it as science, but you have to understand the limitations. That's all.
Q Based on the limitations from Porter and Jick, does it support the statement that the de novo development of addiction when opioids are used for the relief of pain is low?
A I don't know on what basis they -- there's no reference here. So I don't know on what basis they're making this statement.
Q You're a doctor here to testify about the support for J&J's statements. So I'm asking you whether or not J&J believes that Porter and Jick supports this statement that de novo development of addiction when opioids are used for the relief of

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pain is low?
MR. LIFLAND: Object to the form of the question.
A I believe we wouldn't depend upon Porter and Jick. There are other articles where the methodology and the information is laid out in a better manner that we would use to support those statements.
Q (BY MR. PATE) Porter and Jick is a one paragraph letter, right?
A Yes.
Q About a very narrow set of circumstances and observational set of circumstances, right?
A That's correct.
Q It does not deal with chronic non-cancer pain outside of a hospital setting, does it?
A That's correct.
Q So you wouldn't rely just on Porter and Jick to support this statement, would you?
A You're asking my personal opinion?
Q J&J.
A I don't know what J&J relied upon for this statement. There are other articles that support this.
Q I'm asking would J&J rely -- if all J&J

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had was Porter and Jick, could you reach the conclusion that de novo development of addiction when opioids are used for the relief of pain is low?
MR. LIFLAND: Object to the form of the question.
A We would rely on a body of data, and I can't answer upon what we relied upon other than the fact that there are other reports of incidence of addiction. I can't answer your question if that were the only thing, would we rely on that.
Q (BY MR. PATE) Why not?
A Because I don't know the answer to it.
Q Okay.
A It wasn't. It isn't. We have other supportive data where the methodology is better described.
Q You've written articles, right?
A Yes.
Q You write them based on evidence, right?
A Or findings in the clinical trials, that's correct.
Q Experiments you conduct, correct?
A Clinical trials.
Q Okay. Trials?

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A Yes.
Q And things you observe?
A Yes.
Q And whatever criteria you've set forth for what you're trying to find out, right?
A Yes.
Q You understand in order to reach a conclusion, you need to have support for that conclusion, right?
A Yes.
Q The conclusion I'm asking about is de novo development of addiction when opioids are used for the relief of pain is low. Okay?
A Okay.
Q Can you reach that conclusion if the only evidence you have is Porter and Jick?
A Again, I'm asking. You're talking about my personal opinion?
Q Yes.
A No. I would use other evidence.
MR. PATE: Do you want to take a break?
MR. LIFLAND: Sure.
VIDEOGRAPHER: Off the record at 11:01 a.m.
(Break taken from 11:01 a.m. to 11:31

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a.m.)
VIDEOGRAPHER: Back on the record at 11:31 a.m.
Q (BY MR. PATE) Dr. Moskovitz, are you ready to proceed?
A Yes.
Q You understand you're still under oath?
A I do.
Q I wanted to mark the binder that we were looking at while you were answering your questions about Exhibit 4, the binder that you've got in front of you is labeled "Finding Relief References." Correct?
A Yes.
Q Can you slide that to me.
A I'm sorry.
(Exhibit 6 marked for identification.)
Q (BY MR. PATE) Can you just identify what I've marked as Exhibit 6, please.
A These are references in support of some of the statements in the Finding Relief monograph.
(Exhibit 7 marked for identification.)
Q (BY MR. PATE) Dr. Moskovitz, I've handed you a document that I've marked as Exhibit 7. Do you recognize --

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A I can put this aside?
Q Yes, sir.
Do you recognize that document?
A No, I don't. I mean, it's labeled Finding Relief, but I don't recall that I've ever seen this document per se.
Q What's Finding Relief?
A It was information for physicians and patients on how best to manage issues around pain and pain concerns.
Q And it included the monograph that you referred to earlier that we've marked as Exhibit 4 as part of it, right?
A Yes.
Q That also came with a video; is that right?
A A DVD, that's my understanding, yes.
Q Exhibit 7 is labeled "Finding Relief: Pain Management for Older Adults." Then it says, "Video script." Do you see that?
A I do.
Q Is it your understanding that this is the script for the video that went along with that brochure?
A I'll accept that it is. I didn't review it. I didn't look at the DVD.

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Q Have you seen the DVD before?
A I may have. I don't recall.
Q If you'll turn to Page 13, please. If you'll look near the bottom there is -- in the section that is the audio content of the script, the middle column there, there's some text that reads, "Addiction is an abnormal, very unusual state in people with chronic pain, that is a compulsive seeking out or taking opioid medications without regard to the physical, psychological or social consequences of taking those opioid medications."
Do you see that?
A I do.
Q What is J&J's scientific support for the statement that "Addiction is an abnormal, very unusual state in people with chronic pain"?
A Well, to begin with, the first part, "Addiction is an abnormal," by definition addiction is a craving for. So it's not the normal state of pain management. "Very unusual state," I take this to be related to the incidence of, it doesn't occur at -- it occurs rarely.
Q You're saying that by "very unusual," you interpret that to mean it occurs rarely?

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A That's my -- that's my understanding.
Q Okay. So what is the support for the statement that "Addiction rarely occurs in people with chronic pain"?
A We cited a number of references previously, just a few -- the last hour or so and another reference is -- there's a general review of incidence of addiction, and that was the Cochrane report as well.
Q The Cochrane report?
A Yes.
Q Do you have that with you?
A I do. Can we get that?
MR. LIFLAND: Yes. I think it's on the list that you were speaking from earlier. It was just on the flip side of the page. The one that had the four articles that he referenced, it was in No. 5 on the flip side. It's referenced there.
THE WITNESS: Do you know which tab the Cochrane review is under?
MR. LIFLAND: It's No. 14.
THE WITNESS: Yes. I've got it. Okay.
Q (BY MR. PATE) So the support you're claiming for this statement "Addiction rarely occurs in people with chronic pain" are the articles you

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mentioned previously when we were talking about Exhibit 4, correct?
A Correct.
Q Now you've also added the Cochrane review; is that right?
A Yes.
Q That's Tab 14 of what you have in front of you?
A Yes.
Q Let's go ahead and mark what you have in front of you.
A The full binder?
Q Yes, sir.
(Exhibit 8 marked for identification.)
Q (BY MR. PATE) That will be Exhibit 8. Can you identify Exhibit 8 for me.
A It's an index to the supplemental binder with some additional articles. It includes the Fleming article, the Banta-Green article, the Boscarino article, the Fishbain article that we spoke of and the Cochrane review.
Q And where was the Cochrane review published?
A In the Cochrane Database of Systematic Reviews, 2010. It's part of the Cochrane library.

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Q So that was published in 2010. It would not have existed in 2008 and 2009 when the Finding Relief campaign was used, correct?
A Not the review but perhaps the articles that are cited.
Q What article are you pointing to that -- is there any article cited in here that would support this statement?
A So they review a lot of articles, and the articles that meet certain criteria then are summarized in a major summary. That's what Cochrane is known for. It's a summary of summaries. You'd have to go through the -- they speak about reviewing 26 studies with 27 treatment groups. This is under the abstract section, and they would cite the 26 studies.
Q But the Cochrane review itself didn't exist at the time of the Finding Relief campaign, right?
A Correct.
Q That's not something that J&J would have relied on to support any statements it was making at that time, right?
A No, but it supports the statement that the incidence of opioid addiction, especially in a

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preselected population, is low.
Q If you read Page 2, the plain language summary of the Cochrane review, it says, "However, the evidence supporting these conclusions is weak and longer term studies are needed to identify the patients who are most likely to benefit from treatment." Correct?
A Correct.
Q "The evidence supporting these conclusions is weak." That's what the summary of summaries found, right?
A "And longer term studies are needed," correct.
Q Has J&J conducted any longer term studies as suggested by this Cochrane review?
A Not after this. We've had long-term follow-up on a number of our own clinical trials, but, no, not relative to the incidence of addiction.
Q You disagree that longer term studies are needed to determine what the addiction risk of opioids is?
A I believe better data are needed, yes.
Q Better data are needed to determine what the actual rate of addiction is for someone who's on opioids for let's say longer than three months,

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right?
A And relative to what risk factors they had before starting therapy, yes.
Q There are no good studies for longer than three months to determine what the addiction rate of chronic opioid use is there?
A I have to go back to the studies that they review here, whether any of them went beyond three months.
Q Let's talk --
A We have studies that go up to two years and, again, just in terms of the adverse event reporting, we know that the rate of addiction was very low, at least reported rates.
Q You have studies that go up to two years?
A (Witness nods affirmatively.)
Q For what?
A For Duragesic.
Q For Duragesic. Okay. Those are studies where you gave patients Duragesic continuously for a period of up to two years?
A We followed patients who were given Duragesic for a period of up to two years.
Q They were given it continuously that entire time?

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A Yes. It was not an intermittent treatment, yes.
Q Did the patients take it daily?
A I can only speak to the general methodology of the study. Since they were in a controlled clinical trial, they would be seen periodically by the treating physician who would collect the data. So if they discontinued it, they would be dropped from the study and reported as a discontinuation.
So the answer to your question is to the best of my knowledge, there was a cohort who continued for up to two years.
Q Do you know how many?
A I don't.
Q Do you know how they were selected?
A I'd have to go back to the selection criteria for that study.
Q Do you have it?
A We have the long-term treatment with Duragesic. There is also a long-term at least one year follow-up with Nucynta as well. There is "Efficacy of transdermal fentanyl in the management of pain in patients with malignancy." In the notes I see there are patients treated for up to 550 days.

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Q What are you reading from?
A I'm reading from a "Summary of Selected Studies, Research and Analysis of Safety and Efficacy of Duragesic and Nucynta."
Exhibit 3, it's marked, and Tab 1 is "Long-term Safety and Efficacy."
Q And what were you reading?
A Beginning with Page 1 there are studies where patients were followed in the first case three to 156 days, in the second two to 550 days, 36 patients were on fentanyl for more than 90 days and Duragesic 11. The citation on Page 2, an open label long-term follow-up, nine patients who were observed for two years after treatment.
Q These are the Duragesic clinical trials that you were just referring to?
A Yes.
Q Except for the last one was not a clinical trial, was it, the open label long-term follow-up?
A Long term may very well be just long term to a clinical trial. I'd have to go back to the specific trial.
Q Let's make sure we're clear on this. The first tab under 1987 Duragesic NDA, "The study of the efficacy and kinetics of fentanyl delivered via

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continuous intravenous infusion." Do you see where I'm at?
A Yes.
Q That's a clinical trial that J&J performed?
A Yes.
Q Internally?
A Yes.
Q Did you report the results?
A Yes.
Q Did you publish them?
A I don't know. I would imagine we did.
Q The next one is another clinical trial that you -- that J&J performed; is that right?
A Yes.
Q Two to 550 days?
A Yes.
Q The next one is also a clinical trial that J&J performed; is that right?
A Yes.
Q The fourth one you referred to, though, is that a clinical trial that J&J performed?
THE WITNESS: Can we get that study?
MR. LIFLAND: Do you want to look at the notebook?

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THE WITNESS: Yes.
A If this is under Tab 11, that's not what I'm seeing under Tab 11. There's several studies listed under Tab 11. Let me just take a look.
Okay. This is on -- it's under Tab 11, a regional article, "Prolonged treatment with transdermal fentanyl and neuropathic pain."
Q (BY MR. PATE) Tab 11?
A Yes, but it's several pages in.
MR. LIFLAND: If it helps, the summary sheet actually has the page number within the tab where you'll find the reference.
MR. PATE: Okay.
A So this was a clinical trial. I'm just reading from the abstract, "48 patients with non-cancer neuropathic pain who had participated in a randomized controlled trial with intravenous fentanyl infusions received prolonged transdermal fentanyl in an open prospective study."
Q (BY MR. PATE) They looked at a 12 week period?
A I'm sorry?
Q They looked at a 12 week period?
A The original study -- well, the original study was a 12 week dose titration study. So they

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were titrated to a dose that gave them pain relief in a reasonable adverse event profile, and then they were allowed to continue on. It looks like some of the patients continued on for up to two years.

Q Where does it show that?

A That's what I'm looking for. It's the first page of that article. I'd have to go to the full article. I don't have that here.

Q This is just the first page of the article?

A Yes.

Q You did not bring the -- it's not in one of your boxes, the full article?

MR. LIFLAND: I think we just have the abstracts. I think unfortunately we would have had to bring 50 boxes if we brought every article in full.

Q (BY MR. PATE) Let's go back to the clinical trials that J&J performed.

A Let me just go back. So my reading just as the abstract, the original study was the 12 week study, but they're reporting on the patients who continued beyond that period of time. Although I don't have it in this first page, the duration of therapy for the patients who continued in the open

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label portion of the study.

Q So in the first clinical trial that's listed here, and I'm looking at Exhibit 3, there's a three to 156 day clinical trial listed.

A Yes.

Q That was a study of patients who were on Duragesic continuously for up to 156 days; is that correct?

A That's my understanding, yes. Again, I'd have to go back to the study, but generally that's the way we do the trials. There's a period of time where patients are evaluated for critical endpoints, and then in many of the trials we allow them to continue in the trial in an open label fashion and continue to collect data with respect to efficacy and safety.

Q That was not a clinical trial directed at figuring out specifically what the rate of addiction would be with prolonged Duragesic use, was it?

A If you're speaking about that as the primary endpoint, no.

Q It was just a trial that you kept track of how the patients were doing for a period of 156 days, right?

A Up to 156 days, correct.

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Q If a patient happened to report to their doctor that they were an addict as what you call an adverse event, that would be the only way you would know if someone was addicted, someone in that study was addicted, correct?

A Yes.

Q And the same is true for the next clinical trial that you have listed here for Duragesic that went up to 550 days, correct?

A Yes.

Q You were monitoring the patients or their doctors were and reporting any adverse events among other things back to J&J, correct?

A Correct.

Q And if the patients happen to report that they were addicted, that's how you would know and flag an incidence of addiction, correct?

A Correct.

MR. LIFLAND: Object to the form of the question.

Q (BY MR. PATE) You didn't provide the doctors with any specific criteria for them to use or evaluate to identify whether or not a patient was addicted, correct?

A I don't believe so. I'd have to go back

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to the original clinical trial.

Q That trial was limited to Duragesic, right?

A Yes.

Q It is not any evidence of what the addiction rate would be about opioids generally as a class of drug for long-term treatment, correct?

A Correct.

Q Are the doctors who participate in these paid?

A Yes. They would be paid on a per patient basis and for the procedures that they conducted.

Q The same is true of the next clinical trial that's listed here where it says the 36 patients were on TTS for more than 90 days, correct?

A Yes.

Q TTS, is that Duragesic?

A Yes, transdermal therapeutic system.

Q That was focused on Duragesic, right?

A Yes.

Q It has nothing to do with opioids generally as a class of drug, right?

A It was focused on Duragesic, that's correct.

Q And if a patient happened to report that

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they were addicted to their doctor, that would be reported back to J&J, right?

MR. LIFLAND: Object to the form of the question.

A Any adverse event including an adverse event of addiction.

Q (BY MR. PATE) And that's how you have -- whenever you've answered questions, we saw low incidences of addiction, that's what you're basing that on, right?

MR. LIFLAND: Object to the form of the question.

Q (BY MR. PATE) The reports that you got from these clinical trials?

A No. I said that the clinical trials is one aspect of understanding rates of addiction certainly for Duragesic, but that we had other publications that cited low rates of addiction particularly in patients with low or no risk factors.

Q My question wasn't clear.

When you were discussing these clinical trials specifically and you said that we had clinical trials that showed low numbers of addiction, are you with me?

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A Yes.

Q You said that?

A Yes.

Q You're basing that on these reports that you get from these doctors that we've been talking about about these patients, right?

A Yes.

Q Not any independent review that you're doing of those patients or their symptoms, right?

A Yes, that's correct. I think we also spoke about there was a report on iatrogenic addiction that Janssen was asked to do for a regulatory authority and which also showed a low rate of iatrogenic addiction.

Q For the clinical trials, these three clinical trials for Duragesic, were there a specific list or types of adverse events that were provided to the doctors for them to report?

A No. These are spontaneous reports. So unless there is an adverse event of interest, in almost all the clinical trials you would -- these would be spontaneously reported adverse events.

Q You agree that a person can become addicted to Duragesic even when they take it as prescribed by a doctor, correct?

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A That's in the package insert. We do describe that that's possible.

Q And a person can continue to stay on it without that doctor realizing that they've become an addict, correct?

A Potentially. One of the things we do is try to educate physicians to understand addictive behaviors and try to monitor for those.

Q You didn't provide anything to these doctors for these clinical studies for them to specifically monitor for addiction, did you?

A I was not involved with the clinical trials. So I can't answer that. But based upon what I know of clinical trials, we would have instructed them to report spontaneous adverse events.

Q Which includes a whole lot more than just addiction, right?

A Absolutely, any adverse event.

Q What's the report on iatrogenic addiction that you mentioned?

A I think we brought that up at the last deposition as well. We were asked to summarize iatrogenic addiction and we have the report.

MR. LIFLAND: Tab 6 in the binder.

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MR. PATE: Thank you.

Q (BY MR. PATE) This was a study that J&J did for Duragesic specifically?

A I wouldn't call it a study. It's a review of data that were available to the company through adverse event reporting or anything that was reported to the company even outside of clinical trials.

Q So outside of something that would have been reported to J&J?

A Well, it would have been reported to J&J or we would have found it in the literature. So there's a comprehensive review of literature, there's adverse event reporting in the clinical trials, there are spontaneous calls to the safety group, and there's a review of anything that might be reported to the FDA as well.

Q It's not a clinical study?

A It's not a clinical study.

Q You didn't gather a group of patients and put them on Duragesic for three years, right?

A That's correct.

Q And see what happens, right?

A That's correct.

Q See how many become addicted, right?

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A That's correct.
Q You've never done that, right?
A Again, so you're speaking about a clinical trial with addiction as the endpoint?
Q Yes.
A No.
Q You agree that addiction to opioids can ruin someone's life, right?
A By definition it's a craving that impairs their ability to function normally.
Q It can lead to aberrant behaviors?
A Yes.
Q It can lead to some very disturbing behaviors, correct?
A It can lead -- yes, absolutely. It can lead to death.
Q It can lead to their death, right?
A Yes.
Q It can ruin the lives of their family members, right?
A It can, yes.
Q I've got a book here called Responsible Opioid Prescribing. Have you ever seen this?
MR. LIFLAND: Do you have any other copies?

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MR. PATE: I don't actually.
THE WITNESS: I may have. I don't recall.
MR. LIFLAND: Can I take a quick look at it?
THE WITNESS: Yes.
Q (BY MR. PATE) If you'll turn to Page 63 for me. Are you there?
A Yes.
Q There's a table here. This is a page about pseudoaddiction. Are you familiar with this?
A Yes. I'm familiar with the concept of pseudoaddiction.
Q Are you familiar with this table that you see on Page 63?
A Yes. I'm aware of behaviors that are flags for addiction and some more so and some less so, yes.
Q This table is claiming that the behaviors on the left are less indicative of addiction, right?
A Yes.
Q Meaning they're more indicative of pseudoaddiction?
A No. It doesn't say that they're more indicative of pseudoaddiction. It just says that they're less indicative of addiction.

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There are other reasons that patients might exhibit behaviors. They may be hoarding because they worry that they're not going to be able to access it. They may be somewhere where they can't get ahold of their opioid medications.
Q We'll talk more about this table and pseudoaddiction as a concept later.
But you agree at least that according to this table on the left, these are -- the behaviors are less indicative of addiction, right?
A That's how the authors posit them, yes.
Q The ones on the right are more indicative of addiction, right?
A Yes.
Q You agree that the behaviors on the right are aberrant behaviors, right?
A Yes.
Q That they're disturbing behaviors?
A I think many people would consider them to be disturbing behaviors, yes.
Q You wouldn't want that to happen to anyone that you know, would you?
A I wouldn't want that to happen to anyone I know.
Q Right. Let's go through some of them.

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One of the symptoms or behavior that's indicative of addiction that's listed here is if you become an addict you might perform sex for drugs, right?
A One of the way -- one way of getting access to your drugs would be to prostitute yourself.
Q Right. Or that you might prostitute other people to obtain drugs?
A Yes.
Q And that you might forge prescriptions?
A Yes.
Q Or steal money to obtain drugs?
A Yes. I grant you, these are all behaviors that are indicative of -- more indicative of addictive behaviors.
Q And those are all behaviors that can happen to someone who becomes addicted to an opioid, right?
A Yes.
Q Would you agree that it would be -- let me back up.
I asked you whether or not J&J has ever put a group of people on Duragesic for a number of years to see how many get addicted. Do you remember

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that?
A Yes.
Q You said no, right?
A Yes.
Q It would be -- the risks and the dangers to someone if they become addicted to opioids are great, aren't they?
A Yes.
Q We've just seen a number of them that are horrible that can happen to you if you become an addict, right?
A Yes.
Q You agreed that if you become an addict, you may even die, right?
A Yes.
Q It would be unethical to even conduct a study and force people to take Duragesic for a number of years to see how many become addicts, wouldn't it?
A I'm sorry. I'm not following you. So it would be -- you're saying it would be unethical to force individuals to take an opioid like Duragesic to see how many of them would become addicts?
Q Correct.
A It would be unethical to force anyone to

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take any medication.
Q And specifically with an opioid, the risks of what can happen to you if you become an addict are extreme, aren't they?
A They can be, yes.
Q They're deadly?
A They can be, yes.
Q And they can force you to become a criminal?
A If you are addicted, yes.
Q I want to be clear when I use the term "force," I don't mean physically hold someone down and force them to take the medication. So I just want to make sure that we're talking about the same thing.
It would be unethical to conduct a study where you required the patients to take that drug for that extended period of time to determine if they would become an addict, wouldn't it?
A All of our clinical trials allow patients to discontinue therapy at any time. No clinical trial forces a patient to take a medication for any proscribed period of time without any possibility of exiting the trial.
MR. BOWMAN: Drew, I just got an email

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that somebody dropped off a folder for you. Do you need that or do you want to wait for a break?
MR. PATE: We can wait for a break. Thank you, though.
A May I set this aside?
Q (BY MR. PATE) Sure.
(Exhibit 9 marked for identification.)
Q (BY MR. PATE) I've handed you what we've marked as Exhibit 9. Do you recognize that document?
A I do.
Q What is Exhibit 9?
A It's background material to a website that was developed for physicians that they can access information on pain management.
Q That website was called "Prescribe Responsibly," right?
A Yes.
Q It was sponsored by J&J, right?
A Yes.
Q It was funded by J&J?
A Yes.
Q It was created by J&J?
A With input from experts in the field of pain management.

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Q The content was drafted by J&J, right?
A Yes.
Q And approved by J&J?
A Yes.
Q It provided information about how to prescribe opioids, correct?
A It provided information about pain management including the use of opioids, how to assess pain and other options for treating pain.
Q If you would turn to the page that ends in 070. This is about opioid withdrawal assessment, correct?
A Yes.
Q It states that, "Opioid withdrawal symptoms are usually not medically serious."
Do you see that?
A Yes.
Q "But can be uncomfortable and may need clinical management." Correct?
A Yes.
Q Have you ever known anyone who is going through opioid withdrawal?
A I'm aware of friends' offspring who were addicted, but I can't say that they went through opioid withdrawal. So, no. We did measure this in

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some of the clinical trials. So, in that sense, we did look at it.
Q Have you ever seen an infant that's going through opioid withdrawal?
A On television. No, I did not personally.
Q What is the scientific support for claiming that opioid withdrawal symptoms are usually not medically serious?
A Well, I can cite for you that in our clinical trials where we followed opioid withdrawal we didn't see by adverse event reporting serious opioid withdrawal symptoms. I'm not aware of other data.
Q Your clinical trials that we looked at for Duragesic?
A And for Nucynta.
Q Anything else?
A No.
Q Were you specifically looking for or did you look for whether or not any withdrawal symptoms were medically serious?
A We did for -- well, we followed the clinical opioid withdrawal scale for tapentadol, for Nucynta, and they are rated on severity.
Q How so?

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A I'd have to go back to the COWS, but they are rated based upon how severe the symptoms are. So there is a rating scale that's used for that, and it's reported how many patients had mild, moderate, severe withdrawal.
Q That was for Nucynta?
A Yes.
Q That was not done for Duragesic, correct?
A I don't recall that it was ever done for Duragesic.
Q It was certainly not done for opioids as a class of drug, was it?
A I can't speak for other opioids.
Q This is speaking about other opioids, though.
A I don't know.
Q This says, "Opioid withdrawal symptoms are usually not medically serious." Correct?
A Correct.
Q It doesn't say Nucynta opioid withdrawals -- or Nucynta withdrawal symptoms are usually not medically serious, does it?
A No.
Q It doesn't say Duragesic withdrawal symptoms are usually not medically serious, does it?

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A No, it doesn't.
Q It says, "Opioid withdrawal symptoms are usually not medically serious." Correct?
A Correct.
Q This was a statement that J&J wrote, correct?
A Yes.
Q And you are not aware of J&J ever actually studying whether or not opioid withdrawal symptoms are medically serious, are you?
A Opioids in general, no. We didn't do a study per se. Whether there was literature to indicate that, I don't know.
Q Similarly, J&J never did a study to determine whether "withdrawal symptoms can be avoided or eased by slowly tapering the opioid dose." Correct?
A Not a study per se, but that was widely reported in the literature on how to taper patients who are going off of opioid therapy.
Q Are you familiar with a website called PainKnowledge.com or, excuse me, PainKnowledge.org?
A No.
Q Is that a J&J website?
A I'm not familiar with the website.

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Q What kind of doctor are you?
A Internal medicine with a specialty in infectious diseases.
Q You said that you have never personally seen an infant who's going through opioid withdrawal, right?
A Not that I recall. If it had been part of my internship, residency training, I don't recall it.
Q You're aware that that can happen?
A Oh, yes.
Q Infants can be born addicted to opioids?
A Yes. And package inserts now have that as a warning.
Q Those infants when they are born can have very serious medical conditions, can't they?
A Yes.
Q They can go through very serious withdrawal symptoms, can't they?
A Yes.
Q Withdrawal related to addiction to opioids, right?
A Withdrawal related to -- they're dependent on opioids at the time of birth and then it's the withdrawal from the dependency.

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Q You would never tell one of those --
A I'm sorry. I just want to clarify because you used the term addiction for the infants.
Q Dependence.
A Okay.
Q A baby born with opioid dependence can go through very medically serious withdrawal symptoms, can't they?
A Yes.
Q They can die, can't they?
A They can.
Q They can go through extreme pain, can't they?
A I haven't studied it, but I don't know so much about the pain aspect of it. Certainly the symptoms of withdrawal can be severe.
Q They can have seizures?
A Yes.
Q And they're required to have around-the-clock, if it's available, around-the-clock NICU observation, correct?
A I would anticipate in severe cases they would need continuous support for the period of time where they're weaned.
Q You would never tell a parent of one of

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those children that the opioid withdrawal symptoms that that baby was going through against their will is not medically serious, would you?
MR. LIFLAND: Object to the form of the question.
A No, but the infant was born to a parent who took the opioid.
Q (BY MR. PATE) That was not my question.
A I understand.
Q My question is about the child who is born opioid dependent and goes through very serious withdrawal, you would never tell the parent or anybody that that wasn't medically serious, would you?
MR. LIFLAND: Object to the form of the question.
A In the cases where there's been long-term exposure, yes, infants who were born to parents who get occasional drugs but aren't born with a neonatal withdrawal syndrome.
But I would agree with you that there are infants who have severe withdrawal when they've been exposed to opioids in utero for an extended period of time, yes.
Q (BY MR. PATE) Have you treated anyone

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addicted to opioids?
A Personally, no.
Q Have you treated anyone dependent on opioids?
A Yes. As part of my internal medicine internship residency, yes.
Q Did you -- did that patient go through withdrawal?
A It was so long ago, I can't recall the specifics. I'm sorry.
Q Have you ever heard the term "dope sick"?
A No.
Q Would you tell a patient who is addicted to opioids and going through withdrawal that their symptoms were not medically serious?
A I would assess the symptoms. I wouldn't just offhand speak about whether it was or wasn't serious. If the patient was reporting serious withdrawal, I'm going to evaluate the patient based upon what he or she is reporting to me.
Q Would you tell a patient that opioid withdrawal symptoms are usually not medically serious?
A Again, this is hypothetical. I know that patients who have been on opioids for extended

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periods of time need to be tapered off slowly, and there are some recommendations on how to do that.
So if I were in that situation, that's the discussion I would be having with the patient. When you come to a period where we're going to take you off of the opioids, we're going to do it slowly and monitor you so that you don't have serious symptomatology from the withdrawal.
Q You cannot always prevent the serious symptomatology, using your term, from the withdrawal, can you?
A I've not treated those patients. So I can't speak from firsthand knowledge. There are patients who experience significant symptoms of withdrawal, particularly if they're not tapered slowly.
Q Is there any scientific support for the statement that opioids are less than 1 percent addictive?
MR. LIFLAND: Object to the form of the question.
A If you go to the literature and you look at subsets of patients, particularly patients who come in without a history of alcohol use, smoking, other addictive behaviors, I believe that there are

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rates that show the potential for addiction is in the range of 1 percent or less.

Q (BY MR. PATE) In those narrow specific circumstances?

A Yes. You look for risk factors with patients.

Q My question is different. My question is there is no study that has been done that would support the statement opioids are less than 1 percent addictive, is there?

MR. LIFLAND: Object to the form of the question.

A My understanding of the summaries that we provided, the various studies that looked at rates of addiction, the rates of addiction were, again, depending upon the background of the individuals, but overall all-comers, anywhere from the 2 to 5 percent range. So that's not less than 1 percent.

Q (BY MR. PATE) So the answer to my question then is yes, you are not aware of any scientific support for a statement as broad as opioids are less than 1 percent addictive, right?

MR. LIFLAND: Object to the form of the question.

A Most of what I've seen gives you a range

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depending upon the background of the patients, but not in the overall universe of patients that are studied, those ranges tend to be above 1 percent.

Q (BY MR. PATE) And those ranges are not as broad as just using opioids, are they?

A I'm sorry.

Q Every study you're talking about, every study you've looked at or cited at any point today is looking at a specific group of patients, isn't it?

A Well, in the methodology they speak about the patients that they looked at.

Q Right. There's a specific -- there's a methodology for all of those studies, right?

A Correct.

Q None of those studies are broad enough to look at opioids generally for any patients and how they're used, are they?

MR. LIFLAND: Object to the form of the question.

A Again, I'm not -- so they report on large cohorts of patients. So I'm not understanding your question that these are -- including the Cochrane review, which is a review of a lot of other studies, I'm not clear on your question.

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There are a variety of subjects who were exposed to opioids who were studied in all these various studies. Could you clarify your question?

Q (BY MR. PATE) Each study is limited to the circumstances of that study?

A And that's described in the methodology.

Q You agree with that?

A Yes.

Q And they should not be exaggerated beyond what those studies were actually about, right?

MR. LIFLAND: Object to the form of the question.

A I think that by reading the methodology, you understand the limitations of those studies.

Q (BY MR. PATE) So a company shouldn't take a limited study and then make an unlimited statement, should it?

MR. LIFLAND: Object to the form of the question.

A Some of those studies looked at wide cohorts of patients who were exposed to opioids.

Again, how those studies were used, the methodology behind those studies in a number of instances indicated that these are unselected patients who are exposed to opioids over some period

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of time. That might be construed as a broad cohort of exposure to opioids, but you would need to look at the methodology to understand those limitations.

Q (BY MR. PATE) Would you personally make the statement that opioids are less than 1 percent addictive?

MR. LIFLAND: Object to the form of the question.

A I would quantify -- qualify that with whether you had a patient who had risk factors, what were the risk factors, but overall I would not make that overall statement myself.

Q (BY MR. PATE) Would you make the statement that opioids -- opioids are virtually non-addictive?

A Are virtually non-addictive, that's the first time I've heard that terminology. I personally would not make that statement.

Q You would not recommend Janssen make that statement either, would you?

A I didn't make those recommendations.

Q And you wouldn't now as a paid expert for them, would you?

A I wouldn't now.

Q Have you ever heard the expression that

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pain soaks up the euphoria of an opioid?
A No, I have not.
Q Is that a statement that has any scientific support as far as you're aware?
A I'm not -- I've never heard of the statement. So I'm certainly not aware of what support that statement might have.
Q Are you aware of any scientific support to say that there's no risk of addiction when opioids are taken under the care of a doctor?
A No, absolutely not. Even the package insert indicates that there is a risk of addiction even in a properly managed patient.
Q And that's true for any opioid, not just opioids generally, right?
A I'm sorry. So you're saying -- well, I'll speak to our opioids that's in our package insert, and that's my understanding for any opioid.
Q For any opioid there is still a risk of addiction even when it's taken under the care of your doctor, right?
A Well, I mean, we can really go into great detail, but there are opioids that are over the counter right now. Loperamide is an opioid.
Q Schedule II.

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A Okay. Thank you. That's correct.
Q Is it true to say related to opioids that the potential for addiction is in the patient, not the opioid?
A This is the first time I'm hearing that statement.
Q That's not true, is it?
A There are risk factors that need to be considered because patients have greater or less or lower risk of addiction. So, I'm sorry, can you restate your question?
Q Let me just -- you said you never heard it before. So I'll repeat it. Maybe that will help you get comfortable with it.
A Okay.
Q The potential for addiction is in the patient, not the opioid. That's not a true statement, is it? Opioids carry the risk of addiction regardless of the patient, don't they?
MR. LIFLAND: Object to the form of the question.
A And certainly if we speak of Schedule II opioids, that's true. There is a risk of addiction with any Schedule II opioid.
Q (BY MR. PATE) Right. They all come --

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they come from opium, right?
A They are opiates, yes.
Q And the same thing heroin comes from, right?
A They may be synthetically made, yes.
Q And so they can be addictive?
A Yes.
MR. PATE: Do you want to take a lunch break?
MR. LIFLAND: Sure.
VIDEOGRAPHER: Off the videotaped record. The time is 12:38 p.m.
(Break taken from 12:38 p.m. to 1:39 p.m.)
VIDEOGRAPHER: Back on the record at 1:39 p.m.
Q (BY MR. PATE) Dr. Moskovitz, are you ready to proceed?
A Yes.
Q You understand you're still under oath?
A I do.
Q What is pseudoaddiction?
A It's a term that has been described as patients who may present with signs that sometimes can be considered to be signs of addiction, they want more opioids but, in fact, are not due to

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addiction. It may relate to an underlying need for more pain medication for a variety of reasons.
So by definition it's not addiction. Once the pain is adequately treated and it's a diagnosis made retrospectively, the patient is adequately treated for his or her pain and proceeds with the standard course of therapy.
Q Is it a real thing?
A It is widely described in the literature. In fact, it's in the package inserts for all of the Schedule II drugs.
Q Pseudoaddiction is in the package inserts for all Schedule II opioids?
A The concept, the concept of pseudoaddiction can be found in the package insert.
Q Let's break that down first. Is the term "pseudoaddiction" in all of the package inserts for Schedule II opioids?
A Not the term "pseudoaddiction," but the definition, the conceptual idea that there are patients who may be exhibiting behaviors of opioid seeking but, in fact, are doing so because they have inadequately treated pain.
Q Is the term "pseudoaddiction" anywhere in any label for a Schedule II opioid?

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A Not to my knowledge. But as I said, the concept is unequivocally there.
Q You're saying the concept of pseudoaddiction is in every single label for every single Schedule II opioid?
A To the extent that I'm aware that the Schedule II opioid, certainly the long-acting opioids, I won't speak for the short-acting, have a uniform package insert, it's in there.
Q Did you bring those with you today?
A Yes. We have an example of the latest Duragesic.
Q While he's looking for that, you first said that the concept of pseudoaddiction was in every Schedule II opioid product insert, right?
A Let me qualify that to say long-acting opioids where the package insert now has been standardized across all of the long-acting Schedule II opioids.
Q So the first time you misspoke and now it's long-acting opioids are limited to or have some concept of pseudoaddiction in them? That's what you're saying?
A Yes. I'm simply not aware of the others. I'm aware of the standardized wording around the

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long-acting opioids.
Q Can you list every long-acting opioid that you're referring to?
A Long-acting oxycodone, long-acting hydromorphone, long-acting fentanyl, long-acting hydrocodone, hydromorphone, Nucynta, tapentadol.
Q Any others?
A Those are the ones that come to mind.
Q You said that this concept is now uniform in the long-acting opioids. When did that happen?
A Around -- well, there's class-wide labeling for the opioids in 2014.
Q Prior to 2014, was the concept of pseudoaddiction, according to you, in all Schedule II long-acting opioid labels?
A I can't speak to others. So I don't know.
Q Was it in any prior to 2014?
A I don't know.
Q So when you said it's in every single long-acting opioid package insert, you're talking about from 2014 forward?
A Yes.
Q Your lawyer has handed me a document that I think you're looking at. What is this document?
A Selected support for statements and

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representations regarded pseudoaddiction.
(Exhibit 10 marked for identification.)
Q (BY MR. PATE) If you'll hand me the one that you have, I'll mark that as Exhibit 10.
What are you looking at in Exhibit 10?
A I'm looking at the package insert. This is under Tab 2, and it's Section 9.2, "Abuse."
And in the third paragraph you'll see the end of the third paragraph speaks about, "Preoccupation with achieving pain relief can be appropriate behavior in a patient with poor pain control."
Q "Preoccupation with achieving pain relief can be appropriate behavior in a patient with poor pain control."
That's what you're referring to?
A Yes.
Q Your testimony is that that is pseudoaddiction?
A That that represents -- yes. Pseudoaddiction, as I defined it, is behaviors associated with which is preoccupation, the patient is exhibiting behaviors that might look like addictive behaviors. But when they get appropriate pain relief, then those behaviors stop.

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Q Do you have that Responsible Opioid Prescribing book in front of you still?
A Yes.
Q If you'll turn to Page 62 and 63. Do you agree that the behaviors that are described on Page 62 in the bullets are common signs of pseudoaddiction?
A I wouldn't say common. I would say that there are behaviors that look like behaviors that would be exhibited that may be indicative more or less of addiction, but, in fact, when you take a careful history and you determine that it's because the patient is not receiving adequate pain relief, you may make the decision to change the dose or change the drug that the patient is on, and then the diagnosis can be made retrospectively. So you may see behaviors that look like addictive behaviors, behaviors that are listed here.
Q One of the first common signs listed is requesting analgesics by name. Do you see that, Page 62?
A Yes.
Q You agree that's a -- do you think that's a symptom of pseudoaddiction?
A As I said, I'm just speaking in a general

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sense that there are behaviors associated in some cases with addiction that may be because the patient is being inadequately treated.

Q Does J&J agree with the description of pseudoaddiction and the behaviors that are listed in this book?

MR. LIFLAND: Object to the form of the question.

A I won't speak with J&J whether it agrees or disagrees. We certainly understand the concept of pseudoaddiction and support the statements that are in our package insert that relate to making sure that you treat the patient adequately. If the patient is exhibiting behaviors that may be indicative, you have to evaluate that patient carefully.

Q (BY MR. PATE) Let's look at the package insert. The package insert doesn't list any actual behaviors, does it?

A No.

Q It doesn't list what preoccupation with achieving pain relief looks like, does it?

A No.

Q This description of pseudoaddiction that's provided in this book Responsible Opioid Prescribing

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lists specific behaviors, doesn't it?

A Yes.

Q It says, "Requesting analgesics by name is a sign of pseudoaddiction." Doesn't it?

A I'm sorry? Repeat your question.

Q The book says, "Requesting analgesics by name is a sign of pseudoaddiction." Doesn't it?

A It may be.

Q It says, "Some common signs of pseudoaddiction are"?

A Right, but it's some. That means you may or may not see those.

Q It doesn't say "may be." It says, "Some common signs of pseudoaddiction are these things." Doesn't it?

A Correct, but not necessarily in every patient. That's why I'm saying "some."

Q The package insert does not say that requesting analgesics by name is appropriate behavior and a sign of pseudoaddiction, does it?

A No. It doesn't go through the specific behaviors.

Q The package insert does not say that demanding or manipulative behavior is preoccupation with achieving pain relief?

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A No. The package insert doesn't say that.

Q The package insert doesn't say that clock watching is appropriate behavior, does it?

A No. It does not.

Q The package insert doesn't say that taking opioid drugs for an extended period is appropriate behavior, does it?

A No.

Q The package insert doesn't say that hoarding opioids is appropriate behavior, does it?

A No. No, it does not.

Q The package insert doesn't say that obtaining drugs from more than one physician is appropriate behavior, does it?

A Of course, it does not.

Q It doesn't say that taking someone else's pain medications is appropriate behavior, does it?

A Of course. It's not appropriate behavior. It's behavior that needs to be assessed.

Q It's behavior that is a sign of pseudoaddiction according --

A It's behavior that may be a sign --

Q Let me finish my question, please.

It's behavior that's documented in this book as being a sign of pseudoaddiction, isn't it?

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A In some patients.

Q And Janssen supports this book, don't they?

A In the general sense that it's written by a recognized expert in pain medicine, yes, we support the concepts.

Q You've also supported the promotion of this book and it's guidelines, haven't you?

A I don't know. I'm sorry. I simply don't know that.

Q Does the label say that using more opioids than recommended is appropriate behavior?

A The label states exactly what I said it states, that preoccupation can be appropriate behavior.

Q The label does not state that using more opioids than recommended is appropriate behavior, does it?

A No.

Q The label does not state that aggressively complaining to your doctor for more drugs is appropriate behavior, does it?

A I'll grant you it doesn't give the specific behaviors that are listed in here.

Q Your testimony is that this one sentence

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about preoccupation with achieving pain relief is the same thing as the pseudoaddiction concept that we see in this book?

A Conceptually, yes. You need to assess a patient who has a preoccupation with achieving pain relief that it can be an appropriate behavior in a patient who is looking to get pain relief. Yes. That conceptually is the same as pseudoaddiction.

Q The label does not list any of the behaviors that are in this book as being appropriate behavior in a patient with poor pain control, does it?

A No. We've established that. It doesn't list the specific behaviors that are listed as possible behaviors that a patient seeking pain relief might evidence.

Q The label doesn't describe anything about pseudoaddiction at all, does it?

A It does not use the term "pseudoaddiction."

Q Your --

A My testimony is that it -- I'm sorry. I was finishing my sentence, that conceptually this is in part what pseudoaddiction is. There's a patient who's preoccupied with obtaining better pain relief,

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and it could look like addictive behavior.

Q Did you write this label?

A No.

Q Did you participate in it being written?

A Well, not the 2014 label.

Q The 2014 label is the only one that you're pointing to that has this concept, correct?

A It's been proposed in other labels. As far as I know, the 2014 label is the only one that has this wording in it.

Q You don't work --

A For us. I don't know for any other company.

Q You don't work for the FDA, do you?

A No.

Q You've never worked for the FDA, have you?

A Correct.

Q You are not responsible for approving this label, were you?

A I was not responsible for approving it.

Q You don't know what the FDA or anyone else meant when it says, "Preoccupation with achieving pain relief can be appropriate behavior in a patient with poor pain control," do you?

A I can't speak for the FDA.

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Q You don't know that that's referring to pseudoaddiction, do you?

A I'm not sure how I could answer that. I read this as conceptually giving the same information that you have in a patient who's preoccupied with obtaining pain relief may exhibit behaviors. It doesn't list the behaviors. I'll grant you that. But conceptually, this is a basis of the concept of pseudoaddiction.

Q What study has Janssen ever done about pseudoaddiction?

A We haven't.

Q Zero?

A Not to my knowledge.

Q You've never done a study about how often it occurs?

A Not to my knowledge.

Q You've never done a study about whether or not it's real?

A We've never done a study on pseudoaddiction.

Q You've promoted the concept of pseudoaddiction, correct?

A Because it's a generally accepted concept among pain management physicians.

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Q You've trained your sales force about pseudoaddiction, correct?

A Probably conceptually, yes.

Q And you've supported doctors who promote the concept of pseudoaddiction, correct?

MR. LIFLAND: Object to the form of the question.

A Promote the concept? As part of pain management, it's like other definitions in pain management, it's a definition that has been accepted as -- because it's been seen. Physicians who treat pain patients see it and make the diagnosis based on a retrospective analysis of the patient who is responding.

Q (BY MR. PATE) And you've supported -- Janssen has supported groups like the American Pain Foundation and the American Pain Society that promote the concept of pseudoaddiction, correct?

MR. LIFLAND: Object to the form of the question.

A Again, I'm not sure what you mean by "promote the use." This is a terminology. It would be the same as saying promote the use of the term tolerance or dependence or addiction. It's a term that's used in pain management. So we support the

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terminology that's well-defined.
Q (BY MR. PATE) Is pseudoaddiction defined in the DSM?
A I don't know.
Q Do you know who came up with the term "pseudoaddiction"?
A The first time I saw it was in a paper.
Q By Dr. David Haddox, correct?
A That's correct.
Q In 1989 he invented the term "pseudoaddiction." Correct?
MR. LIFLAND: Object to the form of the question.
A I'm not sure what you mean by "invented" as opposed to describing conceptually what was seen as behaviors of accessing pain medication and giving it a term.
Q (BY MR. PATE) Okay. He coined the phrase "pseudoaddiction." Is that fair?
A That's the first time I saw it.
Q From Dr. David Haddox?
A From that article, correct.
Let me be clear, though, when you asked at the beginning what other evidence, there are other papers on pseudoaddiction.

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Q We'll get to those.
A Okay.
(Exhibit 11 marked for identification.)
Q (BY MR. PATE) I've handed you a document marked as Exhibit 11. Do you recognize that?
A Offhand, no.
Q Exhibit 11 is the article where Dr. Haddox first introduced and coined the term "pseudoaddiction." Correct?
A Yes. It just doesn't look exactly like the one I had.
Q He called it an iatrogenic syndrome, right?
A Yes.
Q Iatrogenic means it's caused by the doctor's treatment?
A Yes.
Q And Janssen supports or agrees with Dr. Haddox about pseudoaddiction being an iatrogenic condition, don't they?
A Janssen supports the way the term "pseudoaddiction" is generally accepted in pain literature as patients who may exhibit behaviors that look like drug-seeking behaviors, but, in fact, are related to inadequate pain management, and the

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diagnosis can be made retrospectively. So that's what Janssen supports.
Q What's the DSM?
A It's a criteria for making diagnoses, particularly diagnoses that you're going to be putting in medical claims for with the criteria for them.
Q Do you know what it stands for?
A I don't know offhand.
Q You said that pseudoaddiction was a diagnosis; is that right?
A Yes.
Q You believe someone can be diagnosed with the condition of pseudoaddiction?
A Retrospectively, yes.
Q And that that is caused by the doctor's failure to treat their pain, right?
A That it's not failure to treat their pain. These are patients who may be treated for pain but the patient is exhibiting behaviors that may look like addictive behaviors but, in fact, if the patient is assessed properly and the physician makes a determination that it's because the patient is getting inadequate pain relief and may choose to treat the pain with a different modality and the

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patient -- the patient's pain is relieved and they're no longer exhibiting those signs and symptoms of medication seeking, the behaviors that we just spoke about, then you can make the diagnosis of pseudoaddiction retrospectively. That's what happened.
Q It's caused by, according to Dr. Haddox and Janssen, pseudoaddiction is a condition caused by a doctor's failure to adequately treat a patient's pain, right?
MR. LIFLAND: Object to the form of the question.
A You're putting the onus on the doctor. So the doctor only becomes aware that the patient is having inadequate pain management because the patient is exhibiting behaviors that may be suggestive.
The fact that the patient is exhibiting those behaviors may be because he or she is doing more or there's a change in their underlying condition, but ultimately it's because the pain isn't being adequately treated.
Q (BY MR. PATE) So then is it not an iatrogenic condition? Iatrogenic means it's caused by the doctor, right?

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A Well, the doctor -- if the doctor chooses to treat the patient, the patient's increasing pain, and make the diagnosis retrospectively. Give me a moment.

Yeah. In the discussion he speaks about patients who exhibit drug-seeking behaviors where the physician may not be increasing, may not be treating the pain adequately. I think, therefore, he describes it as iatrogenic.

I would say at this point with the knowledge that we have, we understand the concept of pseudoaddiction. I don't know that we would specifically term it as iatrogenic in each case. The physician becomes aware of inadequate pain management.

Q It's not in the DSM, is it?

A I don't know.

Q The solution when a doctor "diagnoses" a patient with pseudoaddiction is to give them more opioids, right?

A That's not what I said. I said that the diagnosis is made retrospectively. In the case that we're describing is a patient who's exhibiting behaviors, drug-seeking behaviors, the physician has to adequately assess that patient.

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The physician in his or her assessment may conclude that the underlying pain has changed, and if he or she believes that the patient is exhibiting these behaviors because the patient needs better pain relief, the physician may choose to accommodate that needed pain relief in some other way, by increasing the dose, by changing the medication.

If the behaviors subsequently cease, the physician can retrospectively make the diagnosis of a pseudoaddiction in that patient. The patient was not addicted. The patient simply needed better pain control.

Q Better pain control by giving them more or higher doses of their opioids, right?

A I didn't say necessarily opioids. They have to assess what's best for the patient.

Q Pseudoaddiction relates to use of opioids, doesn't it?

A It's a term that's used because the patient is exhibiting behaviors, drug-seeking behaviors, and it was coined because the patient who's exhibiting the behaviors generally was on opioids.

Q Right. But you said a minute ago that you didn't use the term opioids and you weren't necessarily talking about opioids.

A No. I said that what the physician may choose to treat the patient with to more adequately treat the pain may not necessarily involve increasing the dose of opioids.

The physician is faced with a patient who's exhibiting behaviors that may look like addictive behaviors. If the physician's assessment of the patient is that the patient is having increased pain for a variety of reasons, like I said, the underlying disease may have changed, the physician is going to -- may make the assessment that he or she needs to do something to address the inadequacy of the pain relief. That may be a change in the dose of opioids. It may be other modalities.

For argument's sake, a patient who has an underlying malignancy and needs radiation therapy, but the addictive behaviors were related to this term of pseudoaddiction.

Q One of the recommended treatments, if you have a condition, there's a treatment for it, right? That's what doctors try to do?

A They assess the condition and determine what's the best course of therapy.

Q You're saying that there is a condition that is called pseudoaddiction, right?

A Let me be clear. I've stated that pseudoaddiction is the diagnosis that can be made retrospectively. So the doctor, when faced with a patient who's exhibiting these behaviors, is considering whether the behavior is related to addiction, addictive behaviors, or whether it's an outcome of inadequate pain management.

In the course of treatment he or she may decide that the most appropriate course of treatment is to address the underlying inadequate pain management.

If by doing so those behaviors stop, you can retrospectively say those behaviors were not addiction; they were pseudoaddiction.

Q So the answer to my question was, yes, there's a condition known as pseudoaddiction, whether it's diagnosed retrospectively or prospectively, right?

MR. LIFLAND: Object to the form of the question.

A Right.

Q (BY MR. PATE) That it has a treatment, right?

A That there is a physician's decision on

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how best to address the patient who's presenting with these behaviors. I didn't say that the patient who's coming in with these behaviors is getting a diagnosis right then and there of pseudoaddiction.

The physician is addressing the behaviors, and in the differential diagnosis he or she is assessing whether that's due to inadequate pain relief, and he's going to address that.

Q He's going to address it by providing more pain relief, right?

A Well, he's going to address it by figuring out how best to address the patient's pain, yes.

Q So if a patient is in pain and the doctor determines that they don't have adequate pain relief, the recommended provision is to give them adequate pain relief, isn't it?

A To the extent possible, yes.

Q Which would -- could include giving them more opioids, right?

A That may be one way, that's correct. There are other -- there are other modalities. He or she is going to assess what's best for the patients.

Q And the factors that those doctors use to determine whether or not a patient is pseudoaddicted

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or is actually addicted are laid out in one place in this book Responsible Opioid Prescribing, aren't they?

A The behaviors that the patient is exhibiting are laid out.

Q And the guidelines given to doctors about how to tell the difference are laid out in this book in one place, aren't they?

A I'm sorry. Repeat the question.

Q You're saying the doctor has to make their diagnosis, right? The patient comes in and they're exhibiting symptoms. Let's just back up.

A Okay.

Q A patient comes in to see his doctor, right?

A Okay.

Q He's exhibiting certain behaviors.

A I'm with you.

Q Some of those behaviors include demanding an opioid by name. He says he wants Duragesic, right?

A May include that.

Q And he's been on Duragesic for a while.

A Okay.

Q And he may be watching the clock in the

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waiting room, right?

A Perhaps.

Q And maybe he told that doctor that he has been taking more of the opioids that he's been prescribed than the doctor told him to, right?

A Perhaps.

Q And he could tell the doctor that he actually took his brother's pain medication because he was in so much pain, right?

A Perhaps.

Q And he might tell the doctor that he's actually been hoarding other people's pain medications from his family members, right?

A Perhaps.

Q And those are all things that that doctor, according to this book, would be advised are part of or symptoms of pseudoaddiction, right?

A No. I said that those are elements that the physician would assess to determine why is the patient exhibiting these behaviors.

One possibility is that the patient is getting inadequate pain relief. There are other reasons for it. Maybe the patient is becoming addicted to the medication, but in the differential the physician should be aware and in the history and

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physical background try to understand why these behaviors are occurring.

Q Does Janssen provide any information to doctors to help them make that diagnosis?

A Only in the general sense of what we've been talking about, the websites, the information about general principles of pain management.

Q Specifically about pseudoaddiction, what material does Janssen provide doctors for them to determine the difference, like in the example I gave, whether or not that patient is pseudoaddicted or actually addicted?

A Well, we spoke about that that's a diagnosis that's made retrospectively. I believe in some of the materials where we talk about the types of pain medication, we state that it's a diagnosis that's made retrospectively, but you need to evaluate that patient carefully.

Q So there's no way to diagnose pseudoaddiction ahead of time? You just have to give the patient more opioids and see what happens?

A That's not what I said. I made it clear that you're assessing. A patient is coming in with behaviors that may be related to addiction, may be related to underlying inadequate management of pain.

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Q My question is --
A You as the physician have to make the assessment what the reason for those behaviors are. If you make an assessment that, you know what, this is a patient where I can see that there is progression of the underlying disease, that the patient is now becoming more active, they've gone back to the gym and now they're complaining about more pain. I might at that point entertain that this patient's pain is inadequately treated, and I may choose at that point to treat the pain differently.
That selection of how I choose to treat the pain might include increasing the dose of whatever pain medication the patient is on or other adjuvant medication, and if those behaviors dissipate, then retrospectively I can say, you know what, that wasn't addiction, that was pseudoaddiction.
Q My question was -- I'm just trying to get to understand this. Okay? So try to stay with me.
A Okay.
Q What education or information does Janssen provide a doctor so that they can make a determination, to help them make a determination

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whether a patient is exhibiting these symptoms is either a pseudoaddict or is an actual addict?
A I think I answered that with the website, with other information that we provide around general pain management guidelines, some of those guidelines speak to this issue of pseudoaddiction.
Q Okay. You're pointing your hands at this as one example?
A Well, this is an example of general pain guidelines.
Q That being the Responsible Opioid Prescribing book that you have in front of you?
A Because you pointed it out.
Q What other materials has Janssen provided to doctors about how they should evaluate pseudoaddiction?
A Do we have the website, materials in the website? So as part of that answer I would say we do provide materials on assessing pain, and the proper assessment of pain would be part of the issue of whether the patient's behaviors are related to a change in underlying pain or whether they're addictive behaviors.
We provide definitions of the various aspects including a definition for pseudoaddiction.

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Q Where do you provide that?
A If you'll look in Tab 1, Page 65.
Q This is from the Janssen Prescribe Responsibly website?
A Correct.
Q It includes information about pseudoaddiction?
A It includes the definition of.
Q On the Janssen website?
A Yes. On Page 63 it's in the narrative.
Q Anything else?
A No. Let's stick with that right now.
Q I asked you what information Janssen provides to doctors to help them differentiate between pseudoaddiction and real addiction, and this is what you've pointed to, this part of the Prescribe Responsibly website, right?
A As part, yes.
Q Do you agree that addiction to opioids is a complicated diagnosis?
A Yes.
Q You would agree that it's hard to diagnose addiction to opioids?
A It's a diagnosis made over a period of time. It's not an easy diagnosis to make.

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Q Many of the doctors who prescribe opioids are not well trained in addiction, correct?
A I can't speak to their training. To the extent that the package insert defines some of the terminology and some of the behaviors and what to look for, the package insert addresses some of these issues, but I can't speak to the training of any individual doctor.
I know that there are some states that require training on pain management issues. Again, I can't speak to any individual physician.
Q You know that lots of doctors who are not addiction specialists prescribe opioids, correct?
A Correct.
Q Including family physicians, right?
A Some do, yes.
Q They treat their patients' pain sometimes?
A Yes.
Q They try to or at times they may use opioids to do that, right?
A Yes.
Q And over the years that has increased since the mid '90s, hasn't it?
A The rate of prescription of opioids has increased from mid '90s to the early 2000s, yes.

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Q Family physicians in your experience having gone through med school aren't provided a whole lot of courses about diagnosing opioid addiction, are they?
A I can't speak to the current state of training. My training was back in the '70s.
Q Are you aware of any standardized training for family physicians about opioid addiction?
A Standardized training. Again, there are states that require training in pain management and opioids. So any physician, any MD would have to as part of CME take that training. There is training that's provided under the REMS program now to physicians. It's not mandated, but it is provided.
Q In Oklahoma family physicians aren't required to take addiction treatment classes, are they?
A I don't know.
Q Are you aware of whether or not they are?
A I'm not aware whether they are.
Q What information did Janssen provide to any Oklahoma doctor about how to tell the difference between pseudoaddiction and addiction?
A The information that we generally provided to all physicians that had accesses to the Prescribe

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Responsibly website, supportive pain management symposia, the package insert.
Now, when you say specifically make a diagnosis, I said it's part of the differential. If you're talking about pseudoaddiction and addiction, we educate around addictive behaviors in some of the materials that we've already discussed. It's up to the physician to decide whether the behaviors the patient is exhibiting might be behaviors of addiction or it may be due to other reasons, such as inadequate pain relief.
Q You've testified that your opioids carry the risk of addiction, right?
A Correct.
Q Even when they're taken under the care of their doctor, correct?
A Yes.
Q Other Janssen witnesses have testified that your job is to educate doctors about your drugs; is that right?
A Correct.
Q You don't provide any education to any or haven't provided any education to any doctor in Oklahoma about how to tell the difference between pseudoaddiction and addiction; isn't that true?

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MR. LIFLAND: Object to the form of the question.
A No. There are definitions in the label that speak to addictive behaviors and in the --
Q (BY MR. PATE) No. The label didn't list any behaviors. You told me that over and over again that the label did not list a single --
MR. LIFLAND: Please don't interrupt the witness, Counsel. You interrupted him mid sentence.
MR. PATE: And you're interrupting me.
MR. LIFLAND: Yes, because you interrupted the witness. Let him finish his answers, please.
A There's nothing about specific behaviors. That's why we created the monograph. That's why we created the website. It was important to us to educate around issues of pain management. Those issues include what are the behaviors that you need to be aware of.
So I would say, yes, part of our mandate was to educate physicians.
Q (BY MR. PATE) The only education you've pointed to so far today about pseudoaddiction and addiction that your company provided or made available is the definition that you pointed to from the Prescribe Responsibly website, right?

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A Yes. That's not to say there's other materials. I may not be aware of it.
Q That Prescribe Responsibly website, did it list any behaviors as far as whether they're pseudoaddiction or addiction?
A I also spoke about our making available tools, tools that spoke to assessing behavior, patients' behavior and pain. I'll get to that.
Certainly in the definitions we give them references. So they're free to look at those references, too.
Q What references?
A When we make the statement on Page 64, Tab 1, on prescriberesponsibly.com references, when reasonable limits and boundaries are placed on a patient and yet he or she continues to step out of bounds, addiction or pseudoaddiction should be considered as a Reference 20. I'm just not seeing it over here. Do we know what Reference 20 is?
MR. LIFLAND: What page are you on?
THE WITNESS: Page 64, Tab 1, and there's a reference to pseudoaddiction as well. That's 25.
MR. LIFLAND: If you look on Page 66, I think you'll see it.
THE WITNESS: I was looking at the wrong

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section. Okay.
A So 20 is. Gourlay and Heit, "Pain and Addiction: Managing Risk Through Comprehensive Care." Heit and Lipman, "Substance Abuse Issues in the Treatment of Pain, Behavioral Approach to Pain." That's a textbook.
Q And you make those resources available to doctors?
A Well, the references are available to them and they're cited.
Q You pointed to the first one, the Gourlay and Heit study, "Pain and Addiction: Managing Risk Through Comprehensive Care." Is that right?
A Yes.
Q That was a study published in 2008; is that right?
A Yes.
Q Who paid for that study?
A I don't know.
Q Did J&J help pay for it?
A I don't think so, but I can't say for certain.
Q Did they help write it?
A No.
Q Did you review it before it was published?

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A No.
Q Did any other pharmaceutical company?
A I can't speak for anyone else.
Q What does it say about how to tell the difference between pseudoaddiction and addiction?
A I'd have to go back to the paper.
Q Do you have it?
THE WITNESS: Do we have this reference, the Gourlay 20 reference? We should. It's listed in here.
MR. LIFLAND: Tab 20.
THE WITNESS: It's in here. I'm sorry.
A So on Page 25, Tab 20, "Abhorrent behavior may also be a function of inadequate pain management."
Then he goes on to, "Pseudoaddiction is a term used to describe a pattern of maladaptive behavior that is driven by inadequate treatment of pain. When pain is treated appropriately, inappropriate behavior ceases."
And in this article he doesn't list out the specific behaviors.
Q (BY MR. PATE) So that article doesn't provide any insight for how a doctor can tell the difference between pseudoaddiction and addiction,

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does it?
A Not in this article, no.
Q That article was written by Drs. Gourlay and Heit, correct?
A Yes.
Q Drs. Gourlay and Heit are listed on the Prescribe Responsibly page as expert authors who received compensation from Janssen, aren't they?
A I'm sorry. Where are you?
Q Page 63 on Prescribe Responsibly.
A As the authors of this section, yes.
Q Those are the same authors of the paper you're pointing to, right?
A Yes.
Q Those are the same authors that J&J paid to write this website, right?
MR. LIFLAND: Object to the form of the question.
A They received compensation for their contributions to Prescribe Responsibly, yes.
Q (BY MR. PATE) Janssen promotes the use of its drugs to primary care physicians, doesn't it?
A To a subsection of primary care physicians, yes.
Q And historically before Janssen sold all

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its opioids, Janssen promoted opioids to primary care physicians, correct?
A To a group of primary care physician, yes.
Q And Janssen did that in the state of Oklahoma, didn't they?
A I'm assuming we did it nationally, including the state of Oklahoma.
Q You're not aware whether or not Janssen promoted their opioids to doctors in Oklahoma?
A I was not involved with where we were sending our sales representatives, but I am assuming that it was nationally, and that would include every state.
Q You don't know of any reason why Janssen would send drug sales reps everywhere except Oklahoma, do you?
A I'm not aware, that's correct.
Q So Janssen sales reps would have promoted to doctors, targeted and detailed Janssen opioids to doctors in Oklahoma, right?
A Yes.
Q Those same sales reps were paid based on the total number of prescriptions that their doctors wrote, weren't they?
MR. LIFLAND: Object to the form of the

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question. Also, beyond the scope of this witness' topics.

You can answer it if you know personally.

A And the answer is I don't know personally how their compensation was.

Q (BY MR. PATE) You're not aware that your sales force worked on an incentive compensation plan?

MR. LIFLAND: Same objections.

A Same answer. I don't know what their compensation was based on.

Q (BY MR. PATE) Regardless of that, when J&J promoted their products to primary care doctors in Oklahoma, the goal is for those doctors to consider prescribing your drugs for patients in chronic pain, right?

MR. LIFLAND: Object to the form of the question.

A The goal is for physicians to treat their patients with pain adequately. If the physician made determinations that the appropriate way to treat the pain was with an opioid, particularly in a patient with chronic pain that otherwise met the definitions that fall within the indications, then one potential drug that might be considered was a

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Janssen product, and we would provide the information about appropriate selection of patients, appropriate monitoring, appropriate dosing of those patients, appropriate monitoring of those patients and appropriate education for those patients.

Q (BY MR. PATE) A doctor's determination or that doctor's determination would be influenced by their education, right?

MR. LIFLAND: Object to the form of the question.

A I would hope that they're educated on how to assess a patient.

Q (BY MR. PATE) And that they rely on that education in order to make those determinations, right?

A They rely on their education, correct.

Q And Janssen believes part of its responsibility is to educate doctors like that about your products, don't you?

A Within the confines of the package insert and what we could use, what we could educate on, yes.

Q And you provided what you call education to primary care doctors for that reason, correct?

A Yes.

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Q And I think we agreed earlier, but addiction is a difficult thing to diagnose, isn't it?

A Addiction can be a very complex diagnosis.

Q What did you do to determine how well those primary care physicians understood addiction to opioids?

MR. LIFLAND: Object to the form of the question.

A We didn't test them. So I can't answer your question. We provided the education.

Ultimately when the REMS program was put in place, there were -- it was the ability to go online and take a test with the REMS program. That wasn't scored by us. So we didn't do any assessmentment other than providing the education.

Q (BY MR. PATE) What did you do to determine how well Oklahoma doctors understood the difference between addiction and so-called pseudoaddiction?

MR. LIFLAND: Object to the form of the question.

A We didn't test physicians.

Q (BY MR. PATE) So is the answer nothing, you didn't do anything to determine that?

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MR. LIFLAND: Object to the form of the question.

A Not to my knowledge.

Q (BY MR. PATE) Did you do anything to determine what doctors in Oklahoma were taught in medical school about pseudoaddiction?

A Not to my knowledge.

Q Or in CMEs in the state about pseudoaddiction?

A Again, I don't know what CMEs were offered in the state.

Q Did Janssen provide CMEs with its information about pseudoaddiction?

A I don't know.

Q What did you -- what did Janssen do to determine what classes were offered at any medical school in Oklahoma to teach the diagnosis of addiction for chronic pain patients taking opioids?

MR. LIFLAND: Object to the form of the question.

A To the best of my knowledge, that's not something that a pharmaceutical company would get involved with. That's the state or the medical school that would determine its curriculum.

Q (BY MR. PATE) But Janssen states that

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it's its responsibility to educate doctors, correct?
A To educate them about our compounds within the confines of what we can speak about relative to Duragesic and our other opioids and, in a broad sense, to provide education around pain management.
Q What funding has Janssen provided for addiction research in Oklahoma?
MR. LIFLAND: Object to the form of the question.
A I don't know the answer to that.
Q (BY MR. PATE) What funding has Janssen provided for pseudoaddiction research in Oklahoma?
MR. LIFLAND: Same objection.
A I don't know the answer.
Q (BY MR. PATE) Has it provided any?
A I don't know.
Q You agree that the risk of -- the risks associated to a patient with addiction, if a patient becomes addicted to opioids, that those risks are high, right, or severe?
MR. LIFLAND: Object to the form of the question.
A Or potentially. I would hope that if the patient who's under the care of a physician who was providing the opioids -- many patients, many

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individuals who become addicted are not under the care of a physician. So let's take that out of the equation for a moment.
But a patient who is being adequately managed by his or her physician, the physician -- if the physician picks up signs of potential addictive behaviors, the physician can address those behaviors before they progress, but it can be severe.
Q (BY MR. PATE) It can be severe. We talked earlier a patient who becomes an addict can die, right?
A Yes.
Q Or they can start prostituting other people to get money to fuel their habit, right?
A Yes. We spoke about the type of behaviors that an addict can exhibit.
Q Right. If someone becomes an addict, they may steal drugs from other people, right?
A Yes.
Q They may do all sorts of aberrant behaviors, right?
A Yes.
Q And so if a physician is wrong and diagnoses someone with pseudoaddiction and gives them more opioids, you've increased the risk that

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that person could become an addict, haven't you?
A I wouldn't characterize it that way. I would say in the course of making the differential diagnosis the physician is assessing what's the proper course of therapy. There are potential risks to any course of therapy that he or she might undertake.
Q The risks if you're wrong about the difference between pseudoaddiction and addiction are severe, aren't they?
A Potentially. But, again, if you're monitoring the -- so if your decision is, in your differential, that the behaviors the patient may be exhibiting, I've taken an adequate history, and I believe that there's reason to believe that the level of pain has increased, and it's my decision that the way to appropriately treat this patient is with a change in their dose of opioids, if they're on opioids, it behooves me to follow this patient carefully and determine whether the behaviors that the patient was exhibiting, in fact, are now meliorated with a change in my pain management.
And if not, then to reconsider whether the diagnosis was pseudoaddiction or whether I may be dealing with something else.

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Q Doctors make diagnoses, right?
A Yes.
Q The diagnoses we're talking about are whether a patient is pseudoaddicted or addicted, right?
A We've spoken that pseudoaddiction is a diagnosis that's made retrospectively.
Prospectively, a physician is faced with a patient who's exhibiting behaviors that may be indicative of inadequate pain management or addictive behaviors. Based upon careful assessment of the patient's history, history and physical, other factors, the physician is going to have to make a decision how to manage that patient.
In the differential diagnosis, if the physician considers that the behaviors may be related to inadequate pain management, I would argue that the diagnosis at the time is inadequate pain management.
Q One treatment promoted by Janssen for inadequate pain treatment is to give them more opioids, right?
A No. I disagree that one -- that we promote giving them more opioids. We promote assessing the patient if the patient is getting

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inadequate pain relief.
Q And if the patient is getting inadequate pain relief, you would give them more pain drugs, wouldn't you?
A That's absolutely not what I said. You have to assess -- part of pain management is assessing why there is a change in the patient's need for pain management.
We spoke previously about it may be due to changes in the underlying disease or changes in their level of activity. It may be the way to treat the patient's pain is with non-pharmacologic intervention or treating an underlying malignancy differently. It's not necessarily increasing an opioid.
Q Is it your testimony that Janssen did not promote the treatment of pseudoaddiction by giving a patient more opioids?
A To the best of my knowledge, we educated on the concept of pseudoaddiction as a diagnosis that can only be made retrospectively and needs to be considered when a patient is presenting with behaviors that may be suggestive of addictive behaviors but may also be due to inadequate pain management.

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I'm not aware that in any instance would we say the answer to inadequate pain management is increase the dose of opioids.
Q You would not agree with that suggested line of treatment, would you?
A The patient has to be adequately evaluated by the physician as to why the patient is exhibiting these behaviors, and part of that evaluation may be that the patient is having more pain that is inadequately treated. It's the differential.
Q Would you or would you not recommend that a patient that presents with pseudoaddictive symptoms receive a higher dose of an opioid?
A Let's unpack that statement.
Q It's a simple question.
A It is not a simple question. I don't see it as a simple question. I'm sorry. Because you said with symptoms of pseudoaddiction -- the symptoms the patient is presenting with are symptoms of behaviors that might be drug-seeking behaviors. You have to make a determination why the patient is exhibiting these behaviors. One differential for that is the patient is getting inadequate pain relief.
The answer to maybe the patient -- okay.

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I've made a diagnosis. The patient is getting inadequate pain relief. The answer to that isn't necessarily give them more opioids. The answer to that is let me understand how I best manage this patient's pain, and there are a variety of ways to do that, not all of which are just increase the dose of whatever they're on.
Q Did Janssen ever promote that that was the right treatment to increase the dose of the opioids that they were on to deal with those symptoms?
MR. LIFLAND: Object to the form of the question.
A I would say not to my knowledge did we ever say that that's the only way to deal with inadequate pain management.
Q (BY MR. PATE) Did you say it was a way to deal with it?
A It's one of the ways the physician has to assess what's the proper response to the inadequate pain management.
Q I'm not talking about assessment. I'm talking about treatment.
A I'm talking about treatment as well. Once you've made the assessment that these behaviors are due to inadequate pain management, you have to make

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the assessment of what's the best way to manage the patient's pain. Your assessment of what's the best way to manage the pain may be that it's appropriate to increase the dose.
Q Okay. If that is the case, all right?
A Okay.
Q The physician decides it's appropriate to increase the dose of the opioids.
A Okay.
Q What happens if he's wrong?
A Once --
Q He has just increased the dose of an opioid on a patient who was not pseudoaddicted, who's actually addicted, right?
A No. We didn't say that. So now you're giving me a case that you're stating, all right, we have a patient here who -- since the diagnosis can only be made retrospectively, we find that those behaviors continue and, therefore, the diagnosis was not pseudoaddiction.
So I'm following that patient. When I increase the dose, if I choose to increase the dose, as part of my management of that patient, I have an understanding with the patient that I'm going to see you and I'm going to evaluate whether this change in

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medication, just as I would do with any other change in therapy, I need to evaluate whether that change in therapy got me to my goal.

It's no different in pain management. I made a change in your therapy. Now I need to evaluate whether that change in therapy got me to my goal. Did we relieve your pain? And by relieving your pain, did we address the behaviors? That's how the physician should be treating the patients.

Q And if the physician gets it wrong because they think the patient was a pseudoaddict, not a real addict, and they upped his opioid dosage, are you with me so far?

A I'm with you. Thank you.

Q Okay. That could cause things like increased risk of respiratory depression, couldn't it, higher dose of an opioid?

A It could, yes.

Q It could --

A It could cause a number of adverse events, one of which is respiratory depression, yes.

Q And a number of other adverse events, right?

A Yes.

Q Some of the risks that we read about in

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this book, increased risk of taking on some of these behaviors of an addict, right?

A You're conflating adverse events with the drug with the behaviors. So if the physician is increasing the -- we've agreed that in this instance that we're talking about, the physician has contemplated that this may be due to inadequate pain relief, is increasing the dose of opioid, agrees with the patient that follow-up to determine whether we've addressed the issue is proper, we've set up a time, we're going to see you back here.

If I've made a determination, if that physician has made a determination that, nope, those behaviors haven't changed, those behaviors are getting worse, then the physician is going to recognize that this wasn't a case of pseudoaddiction. This may be a case of the patient becoming addicted to the drug. I need to follow a different course of therapy.

Q In between those two points in time, though, the doctor was giving him more opioids, right, this patient in this example?

A In this example, yes.

Q And that increases the risks that come with higher opioid dosages to that particular

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patient, right?

A Potentially, yes.

Q And if that person is actually an addict, it could lead to more and more severe addictive behaviors that addicts exhibit, can't it?

A It could lead to -- first of all, I would argue that any time you change any therapy, not just opioids, any therapy, especially if you're increasing the dose of anything you're giving the patient, you increase the risk of adverse events associated with that medication. It's no different from opioids.

In terms of --

Q It is different for opioids? Because the risk of opioids are deadly and severe and can cause somebody to prostitute other people to obtain drugs. All drugs don't do that, do they?

A No, but there are lots of drugs that have very severe adverse events. So let's be careful because any time I increase the dose of a drug, I'm increasing the risk that there are adverse events associated with that.

I go back to what I said before. I need to be in a position, I need to be in a position where the patient understands why I'm choosing to

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increase the dose and what my follow-up is going to be.

It may be that my instructions to the patient is I'm not comfortable with the behaviors that you're exhibiting. I want to see you back here in three days. I want to see you back here in a week. I want you to call me tomorrow and let me know if you have a change in your pain score.

Yes, there are risks associated with it, but to the extent that you follow that patient carefully you can minimize, I didn't say totally do away with, but you can minimize those risks.

Q Can you name me one drug, one other drug, other than an opioid, that carries with it the attendant risks that it could cause someone to engage in human trafficking?

A Barbiturates.

Q Anything else?

A Offhand, no.

Q Janssen has never done a study to determine what -- how often doctors misdiagnose pseudoaddiction, have you?

A No.

Q You're not aware of any studies to try to determine how often doctors misdiagnose

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pseudoaddiction, are you?
A I'm not aware of studies on the success of any physician making any diagnosis to begin with. So the answer to your question is no.
Q About pseudoaddiction?
A About pseudoaddiction, too.
Q For patients who present with pseudoaddiction symptoms or behaviors, what percentage of those patients are actually addicted or are pseudoaddicted?
A Again, I take you back. They don't present with pseudoaddicted behaviors. They present with behaviors that are drug seeking.
The diagnosis of pseudoaddiction is a retrospective diagnosis. It has to be taken into account when you are assessing the behaviors the patient is presenting with.
Now continue with your question.
Q Let's talk about that for a minute. You keep saying that pseudoaddiction is a retrospective diagnosis, but a patient comes into a doctor's office, right?
A Yes.
Q They tell the doctor they're experiencing certain symptoms, right?

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A Well, my assumption is that they're coming in and they're starting out by saying, "I have pain."
Q Right. They're telling the doctor they're having certain symptoms, right?
A Correct.
Q One of those in our scenario is probably pain, right?
A Correct.
Q Doctor, I'm experiencing a lot of chronic pain, I can't get rid of it, right?
A Okay.
Q That patient also is sitting there in the doctor's office watching the clock a whole lot. The doctor might notice that, right?
A Okay. But I would take a step back and so in the discussion the physician is having with the patient, the physician is asking about, "So what are you doing about the pain?" And the patient may be responding, "Do you know what, I'm taking my pain medication a little bit more frequently. I'm taking more pain medication during the day. I upped the dose."
Q Let's use those examples.
A Okay.

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Q The patient says he's in pain and says, "I'm taking more pain meds than you're giving me."
A Okay.
Q "I'm taking them more frequently than you told me to."
A Okay.
Q "I'm doubling the dosages." Right?
A Okay.
Q "I'm also stealing, borrowing," whatever word you want to use.
A You can use stealing. That's fine.
Q "Drugs from my cousin because I'm still in pain."
A Okay.
Q They may present all of those things to the doctor at that time, right?
A Okay.
Q And at that time that doctor has to make a decision and has to decide do I think he's pseudoaddicted and he's just not getting enough pain treatment or may he actually have an addiction problem already? The doctor needs to make that determination right there.
A Here's where we differ. I would argue that the doctor isn't saying, "Is this patient

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pseudoaddicted?" The patient should be asking himself or herself, "Why is this patient exhibiting these behaviors?"
Q You said the patient. You mean the doctor?
A The doctor is asking, "Why is this patient exhibiting these behaviors?"
It may be, "Now, let me take a more comprehensive history of what's happening with your pain. Did you increase your activity? Are you going back to the gym? Let's take a look at the underlying malignancy that you're dealing with. I may send you for some tests."
So I have to address the behaviors that the patient is telling me about.
Q Before that doctor decides to write a script for a higher dose of opioids, he's got to make -- he or she has to make a decision about whether or not they think their patient is an addict or not and simply is not getting the pain relief they need, right?
A They have to make a assessment of why the patient is exhibiting these behaviors. Are they using the drug to get a high? So, yes, there's a continuum, and these may be behaviors that are

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1 indicative of early addiction, correct.
2 Q They also may be behaviors according to
3 your company and other promotional pieces that
4 you've supported that indicate not real addiction,
5 right?
6 MR. LIFLAND: Object to the form of the
7 question.
8 Q (BY MR. PATE) Fake addiction,
9 pseudoaddiction?
10 A I'm not clear on your question. Please
11 repeat it.
12 Q Sure. The behaviors we just listed, the
13 pseudoaddiction materials that Janssen provides,
14 provide the doctor with information that those
15 behaviors may not be real addiction, they could be
16 pseudoaddiction, right?
17 A That the physician should carefully assess
18 the patient to understand why those behaviors are
19 occurring.
20 Q Because it could be pseudoaddiction.
21 A Because the patient may be getting
22 inadequate pain relief.
23 Q Which is the definition of
24 pseudoaddiction, isn't it?
25 A Which is a diagnosis that's made after you

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1 adequately treat the patient and those behaviors go
2 away.
3 So the diagnosis that you're trying to
4 think of the day that the patient is presenting is
5 am I -- is this patient exhibiting these behaviors
6 simply because he or she is having more pain. Let
7 me understand why that might be. Or is this
8 something other than that, that they may be
9 exhibiting addictive behaviors.
10 Q What is the scientific support for
11 pseudoaddiction?
12 A Only that the patient's behaviors resolve
13 with proper treatment.
14 Q There's no study about it?
15 A To the best of my knowledge, no. There's
16 observations about it.
17 Q You're not aware of any effort to
18 determine how often physicians misdiagnose
19 pseudoaddiction retrospectively or prospectively?
20 A I'm not aware of any.
21 Q Janssen hasn't done one?
22 A No. I'm not aware of any studies on
23 making the correct diagnosis in almost any -- for
24 clinical trials we have it, but other than that, in
25 general medical practice, I can't say how often the

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1 correct diagnosis is made or not. No. The answer
2 to your question is no.
3 But let me continue, though. As I said,
4 the physician may be wrong. We recognize that.
5 Q Wrong about what?
6 A About whether the right course of therapy
7 is to increase the dose of opioids should he or she
8 decide that that's the way he or she wants to treat
9 the patient.
10 But the proper way to do that is then to
11 have closer follow-up with the patient to determine
12 whether that took care of the issue.
13 So, yes, there may be misdiagnoses, but
14 the way medicine takes care of misdiagnoses is to
15 change the direction of treatment and then see if
16 that change in the course of direction of treatment
17 achieved the outcome you were looking for.
18 Q The consequences of misdiagnosing
19 addiction to opioids or failing to diagnose the
20 addiction to opioids can be severe for a patient,
21 can't they?
22 A They can be which is why if you choose
23 that course, you should be following the patient
24 even more closely.
25 May I put this aside?

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1 Q Put what aside?
2 A Prescribe Responsibly.
3 Q Sure.
4 (Exhibit 12 marked for identification.)
5 Q (BY MR. PATE) I've handed you a document
6 we've marked as Exhibit 12. Do you recognize that?
7 A I can't say that I recognize this specific
8 piece that you've given me, but the concepts of
9 pharmacokinetics and pharmacodynamics and education
10 around it I do. Again, I don't know whether I've
11 seen this specific piece before.
12 Q It states that it was supported by an
13 educational grant from J&J, correct?
14 A By PriCara, yes.
15 Q And administered by J&J, correct?
16 MR. LIFLAND: Object to the form of the
17 question.
18 A Yes.
19 Q (BY MR. PATE) While we're talking about
20 pseudoaddiction, if you'll turn to the page that
21 ends in 689.
22 A So I also note that on the top there's a
23 designation of credit which tells me that this was
24 a continuing medical education program. Okay. We
25 would have very little input to it.

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I'm sorry. Go on.
Q The page ending in 689.
A Okay.
Q The left side of the page there's a paragraph that starts, "The topics of opioid analgesic misuse and addiction are discussed frequently."
Do you see that?
A Yes, I do.
Q If you move down a few lines you'll see, this is for -- this is a document for pharmacists, right?
A Yeah. I can just make out that the continuing education is for pharmacy education.
Q So going back to that section. It says, "It is important that community pharmacists..." Sorry. The middle of the paragraph.
A I got it.
Q Are you with me?
A Yes, I am.
Q "It is important that community pharmacists, in addition to prescribers, be familiar with the differences between addiction, physical dependence, tolerance, pseudoaddiction and abuse as outlined in Table 8, Page 8. Pseudoaddiction

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typically results from undertreatment of pain. The behaviors associated with pseudoaddiction shown in Table 9, Page 8, are unfortunately frequently misidentified as drug-seeking behavior, whereas undertreated pain should be the top-of-the-mind cause."
Did I read that correctly?
A Yes.
Q What is the scientific support that undertreated pain should be the top-of-the-mind cause when patients exhibit the drug-seeking behavior that's described here?
A I'm not sure what the question is. So this is to pharmacists, and there is contention that they should be aware of this terminology.
Please rephrase the question.
Q What is the scientific support for the statement that patients exhibiting the drug-seeking behaviors described here, that the top-of-the-mind cause should be considered undertreated pain.
Let me start over again.
What is the scientific support for the statement that undertreated pain should be the top-of-the-mind cause for patients exhibiting the behaviors, the drug-seeking behaviors described

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here?
A I don't know. We didn't write this material. We supported it. I'm looking at the two references, 56 and 58. They list two references here.
Q Are you aware of any scientific support for that statement, though?
A Again, I'm not sure what the question is. So a patient who is having inadequate pain relief is going to try to get pain relief. So what's wrong with trying to get pain relief?
Q I didn't say there was anything wrong with trying to get pain relief, sir.
A I'm sorry. Then I'm misunderstanding the question.
Q I asked what's the support for the statement that the top-of-the-mind cause where someone exhibiting the behaviors we see on the next page is that their pain is undertreated?
Let's look at those behaviors. It's referring to Table 9 on the next page, right?
A Let me take a step back --
Q Hold on. Let me ask the question.
A Going back to your previous question. So --

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Q I ask the --
A I'm not reading it the same way.
Q I ask the questions. We'll work through it this way. I'll ask the questions and then you'll answer as best you can. If you need to explain your answer, you're free to, but I'm going to ask the questions. Okay?
A Okay.
Q The table on the next page, Table 9 is what it's referring to, right, "Signs of Pseudoaddiction." Do you see that?
A Yes.
Q The behaviors listed are borrowing drugs from others, correct?
A I can barely make it out. Keep reading.
Q Obtaining --
A Your vision is better than mine.
Q Obtaining prescription drugs from nonmedical sources, right?
A Okay.
Q Unsanctioned dosage increases, do you see that?
A I do.
Q Running out of medications prematurely, right?

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A Yes.
Q Requesting higher dosages, right?
A Yes.
Q Requesting specific drugs, right?
A Yes.
Q Hoarding drugs when symptoms are not severe, right?
A Yes.
Q Prescription forgery (may indicate other problems), right?
A Yes.
Q Recurrent prescription loss may indicate other problems, right?
A Yes.
Q Obtaining drugs from multiple medical sources may indicate other problems, right?
A Yes.
Q And stealing drugs may indicate other problems. Do you see all those?
A Yes.
Q Those are all listed in this table under the heading, "Signs of Pseudoaddiction." Correct?
A Yes.
Q My question is what scientific support is there that a patient exhibiting these behaviors that

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the top-of-the-mind cause from that should be undertreated pain?
A Here's where I -- I don't know that I'm reading it the same way because the way I'm reading it, especially because this is to a pharmacist who can't prescribe anyway, is that these may be examples of behaviors, but the focus should be on what do I need to do to treat the pain adequately?
I don't know what they're citing over here. We didn't write this piece.
I would venture that these are written by experts in pain management. They see the patients all the time. They have an opportunity to evaluate hundreds of patients, and this is what they see.
Perhaps they have a closer understanding that they have a cohort of patients who at one point or another exhibited these behaviors, and in their assessment of the patient when they made an assessment that the patient's pain was inadequately treated, the behaviors went away. On the basis of that experience they're writing it.
But I can't answer for the writers.
Q Janssen put their name on this document, right?
A We supported it. It was financial

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support.
Q And you put your name on it?
A It was independent of us in terms of writing it.
Q You put your name on the document, right?
A Yes. We supported it.
MR. LIFLAND: Object to the form of the question.
Q (BY MR. PATE) Are you aware of any study that shows that a patient who exhibits these behaviors in Table 9 that the top-of-the-mind cause of those should be undertreated pain or is undertreated pain?
A Let's first take a step back. It's not "is" undertreated pain, it's "should be."
But, again, I don't know of a study. That's the answer to your question.
Q Thank you.
A These are individuals who are writing on the basis of their experience as well.
If you go back even to the Haddox report, there was a case record. There was a case description of these things. So there are certainly case descriptions that describe the type of drug-seeking behaviors that might be considered to

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be behaviors of addiction. Whereas, when the patient was treated for their underlying pain, those behaviors went away.
Not everything needs a clinical study. Sometimes a clinical observation can make a case for why you might treat a patient one way or another.
Q Are you aware of any clinical observations that show that patients presenting with these behaviors, that the top-of-the-mind cause of that should be undertreated pain?
A Again, the term "top of the mind," no, I'm not, but that consideration should be whether the patient is getting adequate pain relief.
Q Are you aware of any study that shows that those behaviors are frequently misidentified as drug-seeking behavior?
A Again, I'm not understanding the question. So these are drug-seeking behaviors. When you said that they're misidentified as drug-seeking behaviors, they are drug-seeking behaviors.
Q Well, I'm just --
A The question is what's the differential diagnosis? Why is this patient exhibiting drug-seeking behaviors?
Q That may be your question, but that's not

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what the document says. I'm just reading from the document. It's got your company's name on it, and it says that these behaviors are "unfortunately frequently misidentified as drug-seeking behavior."

MR. LIFLAND: Object to the form.

Q (BY MR. PATE) Do you see that?

MR. LIFLAND: Object to the form.

A Frequently misidentified as drug-seeking behavior, yes.

Q (BY MR. PATE) My question is are you aware of any scientific support for that statement?

A No, and we've already indicated that in other cases where they are less likely or more likely. I'm not aware of scientific support that look at the frequency with which a particular drug-seeking behavior may be more or less predictive of other than perhaps the clinical experience of the physicians who wrote the piece, but I'm not aware of a study.

Q Are you aware of anything that indicates that a patient who comes in and the doctor learns that they've been hoarding drugs, forging prescriptions and obtaining drugs from multiple sources, are you aware of any study that indicates that person is more often than not going to be a

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pseudoaddict than an actual addict?

A It's a consideration of why a patient is exhibiting the behavior. The answer to your question am I aware of a study that looks at the predictive value of any of these behaviors, no, I'm not.

Q Are you aware of any study that looks at the frequency of pseudoaddiction versus actual addiction to opioids?

A No. Though, I would again argue that that shouldn't impact on an individual physician in his or her determination for an individual patient what's the right course of therapy for that patient.

Q Why isn't Janssen doing any studies to determine how often people are misdiagnosed with pseudoaddiction versus addiction?

MR. LIFLAND: Object to the form of the question.

A These are clinical determinations, and these are studies or examinations that are best done by the physicians who are treating the patients. This isn't related to any one specific drug either.

Q (BY MR. PATE) Janssen does studies, right?

A Yes.

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Q Janssen does studies about its own drugs, right?

A Yes.

Q Or other drugs on the market, right?

A In comparison to our drugs, yes.

Q You have a responsibility to educate doctors you say, right?

A Yes.

Q About your drugs, right?

A Yes.

Q Addiction is a risk of opioids, right?

A Yes. We state that.

Q You sold opioids for a number of years, right?

A Yes.

Q Why didn't you try to determine what the rate of addiction versus pseudoaddiction was while you were selling opioids?

A I can't answer --

MR. LIFLAND: Object to the form of the question.

A I can't answer why we didn't do a study. We taught that when you're assessing a patient, one of the considerations is what is leading to those behaviors. An assessment of that patient is not a

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statistic.

An assessment of that patient is why is this patient exhibiting these behaviors? If a take a careful history and I exam the patient carefully and I make a determination that this may be due to inadequate pain relief, then I follow a different course of treatment than if I don't make that determination. Statistics don't treat patients.

Q (BY MR. PATE) I've asked you before whether or not Janssen had any studies about the addiction rate of its opioids. Do you remember that?

A Yes.

Q You said you all did some clinical trials that provided some information to you about that, right?

A And we did a summary report of iatrogenic addiction with Duragesic.

Q Janssen never did a study or looked at for its products what the rate of pseudoaddiction was, did you?

A I'm sorry, I'm seeing this in two different terms. There isn't a rate of pseudoaddiction to a particular drug.

Q Because it's made up.

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A I disagree with --
MR. LIFLAND: Object to the form of the question.
A I disagree with that. So if I'm allowed to, if you have pain and you're on a pain medication and you're worried that you're going to be going someplace and you won't have access to it, so you take extra with you, aren't you concerned about treating your pain? So you start to hoard the medication, and then it's up to the physician to determine why that's happening.
I don't understand why the concept is a concept that's being totally dismissed.
Patients who are in pain look for adequate treatment of their pain. There may be other reasons that they're looking for -- that they're exhibiting certain behaviors, but I think it's absolutely one possibility that a patient who is in pain, especially if they're experiencing more pain than they had before, would be looking for pain relief.
Q (BY MR. PATE) Let's try to make this -- break this down a little bit, make it a little bit more simple.
What study did Janssen ever do to determine that someone who borrows drugs from

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another person, how often that person is pseudoaddicted or is actually addicted?
A First of all, that's a reasonable way of addressing the question.
Q Thank you.
A I don't know. I'm not aware that we did any.
Q Are you aware of any studies that anyone else has done about that?
A No.
Q What studies has Janssen done to determine for a patient who starts obtaining prescription drugs from a nonmedical source, what the rate is of that person being a pseudoaddict versus an actual addict?
A Janssen hasn't done any studies. It's presumably something that a pain management group would do. We don't have access to those patients.
Q And you're not aware of any information about that?
A I'm not.
Q What studies has Janssen done about a patient who comes in and presents with unsanctioned dosage increases, meaning they're taking more drugs than the doctor has said they should, right?

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A Yes.
Q For those patients, what has Janssen done to determine the rate at which those people are either pseudoaddicted or actually addicted?
A I'm not aware of any.
Q Are you aware of any studies that anyone else has done about that?
A No.
Q What studies has Janssen done for a patient who comes in and is running out of their opioid medications prematurely to determine at what rate those people are pseudoaddicts versus actual addicts?
A Not aware of any.
Q By Janssen or anyone else?
A Correct.
Q What study has Janssen done to determine when somebody comes in, a patient, and they're requesting higher -- specifically requesting higher dosages of their medication, that that person is a pseudoaddict versus an actual addict?
A Not aware of any.
Q By Janssen or anyone else?
A Correct.
Q What study has Janssen done to determine

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when a patient comes in requesting a specific drug, an opioid by name, that that person is either pseudoaddicted or actually addicted?
A I'm not aware of any.
Q By Janssen or anyone else?
A Correct.
Q What study has Janssen done to determine when a patient comes in and tells their doctor that they're hoarding their opioid drugs when their symptoms are not as severe, that that person is a pseudoaddict versus an actual addict?
A I'm not aware of any.
Q By Janssen or anyone else?
A Correct.
Q What study has Janssen done to determine when a patient comes in and tells a doctor that they've been forging prescriptions or the doctor finds out they're forging prescriptions; are you with me?
A I am.
Q What studies has Janssen done to determine that that patient is more likely to be a pseudoaddict versus an actual addict?
A None.
Q You're not aware of anybody -- by anyone

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else, right?
A Correct.
Q What studies has Janssen done to determine that a patient who comes in and they come in a lot and they're always saying they're losing their prescriptions, that happens sometimes, right?
A Yes.
Q Doctors will hear sometimes from the same patient over and over about how they lost their prescription, right?
A Yes.
Q So they needed to be refilled early, right?
A Yes.
Q This table refers to recurrent prescription loss. Is that what that's referring to?
A Yes.
Q What studies has Janssen done to determine that a patient like that with recurrent prescription loss is more likely to be a pseudoaddict versus an actual addict?
A None that I'm aware of.
Q By Janssen or anyone else?
A Correct.

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Q What study has Janssen done to determine if a patient who comes in and they're obtaining opioid drugs from multiple doctors, what studies has Janssen done to determine that that patient is more likely to be a pseudoaddict versus an actual addict?
A None that I'm aware of.
Q By Janssen or anyone else?
A Correct.
Q What study has Janssen done to determine that a patient who comes in and admits that they've been stealing opioid drugs from someone else, that that person is a pseudoaddict versus an actual addict?
A None I'm aware of.
Q And none by anybody else?
A Not that I'm aware of. May I make a comment, though?
Q Is it in response to one of my questions?
A Yes.
Q Go ahead.
A When you speak of a study, you're talking about getting at a rate of. It's true. A study would help you determine a rate of pseudoaddiction versus addiction if you followed the patient

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prospectively but in no way negates the fact that case record -- reports of patients who have exhibited these behaviors who were subsequently adequately assessed, where the physician made a determination that the behavior I'm seeing is related to inadequate pain management, and then I go ahead and treat the patient's pain adequately and these behaviors dissipate, you only need one case report to make a determination that that's what happened in that case.
The studies that you're speaking about are all valuable, but they get at a rate of pseudoaddiction versus addiction, not a determination of what I need to do in a particular patient, which is what a lot of the educational materials address.
Q The studies I'm talking about don't exist?
A Correct.
Q And Janssen is not providing any money so that they be done?
A Not to my knowledge.
Q Now, the report you referred to, are you aware of any article or anything that looks back at case records to determine this based on those types of reports?

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A I'm not.
MR. PATE: Let's take a break.
VIDEOGRAPHER: Off the videotaped record. The time is 3:35 p.m.
(Break taken from 3:35 p.m. to 3:55 p.m.)
VIDEOGRAPHER: Back on the record at 3:55 p.m.
Q (BY MR. PATE) Dr. Moskovitz, are you ready to continue?
A Yes.
Q You understand you're still under oath?
A I do.
Q I want to mark a couple of things just for the record that you've referenced today so far. You've got the binder in front of you that's labeled "Sources of knowledge regarding abuse, misuse, dependence or addiction."
A Yes.
(Exhibit 13 marked for identification.)
Q (BY MR. PATE) I've marked that as Exhibit 13. Can you identify Exhibit 13, please?
A "Sources of knowledge regarding abuse, misuse, dependence or addiction."
Q Those are all the J&J sources of knowledge that you brought with you today, correct?

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A Yes. Yes.
Q And they're all that you're aware of having prepared for this deposition, correct?
A Yes. This is at a high level. So I didn't bring the full clinical study reports, but at a high level this is the information I'm aware of, yes.
Q And it lists what the reports are that Janssen is aware of?
A Yes.
Q You're just saying it doesn't provide the actual body of the reports themselves?
A Correct.
Q The other large binder that you've referred to once today we referred to as the Prescribe Responsibly binder. Do you recall that?
A Yes.
Q Let's mark that as well.
(Exhibit 14 marked for identification.)
Q (BY MR. PATE) That will be Exhibit 14. If you can identify that for me, please.
A Exhibit 14 is prescriberesponsibly.com references.
Q What is that?
A The backup material for the website that

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was created, the Prescribe Responsibly website.
Q How long did that website exist?
A You can still access it today. I'm not sure when we put it online. I don't recall that.
Q Does the binder contain all the references that have been used on that website over time?
A Yes, I believe so.
Q Does it contain information about or all information about what's been on that website since it was created?
A I don't know.
Q Has the content of that website changed over time?
A I don't know whether the concept -- whether the website has changed over time. I don't know.
Q In the documents that you -- I guess you've called them the high level documents that you brought with you, there is a page in here about "Selected support for statements and representations regarding pseudoaddiction."
A Yes.
Q Do you see that?
A I do.
Q Let's go ahead and mark that. This was a

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document that you brought with you for your testimony today, correct?
A Yes.
(Exhibit 15 marked for identification.)
Q (BY MR. PATE) Did you put this document together?
A I knew of some of the references, but I didn't put it together, no.
Q Who put it together?
A Counsel put it together.
Q We marked the document as Exhibit 15; is that right?
A Yes.
Q Is that all of the support your -- that J&J is aware of for statements and representations it's made about pseudoaddiction?
A Yes.
Q You testified previously that J&J hasn't done its own studies about pseudoaddiction, right?
A Yes.
Q You agree that that is a -- at least a term that was created by Dr. David Haddox, correct?
MR. LIFLAND: Object to the form of the question.
A He gave a term to a concept that was

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understood to be the underlying concept, inadequate pain relief in a patient who was exhibiting these behaviors and the term -- they used the term "pseudoaddiction," yes.
Q (BY MR. PATE) And it came from Dr. David Haddox?
A That's the first time I saw it in the literature.
Q And you saw in the article he at least claims that he's introducing that term, right?
A I'd have to go back to the article itself.
Q Exhibit 11. The first page above "Case report."
A I see it. So you're talking specifically the term pseudoaddiction is introduced to describe the syndrome.
Q Yes.
A Yes.
Q Dr. Haddox now works for Purdue, correct?
A I think I testified I don't know where he is currently. I know that he worked for Purdue. I don't know his current employment.
Q For a number of years you're aware that he was a high ranking Purdue executive, correct?
A Yes. I'm aware of that.

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Q Do you know Dr. Haddox?
A I've met him. So the answer, yeah, I know of him. Yes.
Q You agree with his thoughts on pseudoaddiction?
A I agree that there is a need to assess behaviors that might be considered to be addictive behaviors, but, in fact, upon closer examination and close follow-up are more related to inadequate pain relief.
So that's a concept that I certainly agree with, then it got a name.
Q It got a name from Dr. Haddox, right?
A Yes.
Q And then your company has used that name, right?
A My company and the pain treatment community uses that terminology.
Q So, yes, Janssen uses the term pseudoaddiction, right?
A Yes.
Q You include it in materials you provide to patients and doctors, right?
A Yes.
Q You put it on that website, Prescribe

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Responsibly, right?
A Yes.
Q Purdue also uses that term, correct?
MS. NEWSOME: Object to the form.
A Offhand I don't recall that they've used the term, but I wouldn't disagree with that.
Q (BY MR. PATE) Their doctor, David Haddox, is the one that came up with it. Safe to assume that they support pseudoaddiction also, right?
A Well, I --
MS. NEWSOME: Object to the form.
A I don't know if he worked for Purdue at the time he wrote this article. So, again, I simply don't know whether -- how Purdue uses the term. It's a term that's in general use in pain management and widely used.
Q (BY MR. PATE) Widely used by pharmaceutical companies?
A Widely used by pain specialists in pain management, as a concept in pain management.
Q Did you say pain specialists and pain management?
A In the universe of pain management -- I mean, you just referred to the pharmacy piece. So it's similar to tolerance, physical tolerance and

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addiction. Other terms that are used in pain management, pseudoaddiction has entered the lexicon as an understood concept.
Q And it's a concept that originated with David Haddox, right?
A The term originated with David Haddox --
Q Let's use an example.
A -- and David Weissman.
Q You saw the term and the concept discussed in the Responsible Opioid Prescribing book, correct?
A Yes.
Q And we discussed how it was described and the behaviors listed in that book, correct?
A Yes.
Q And if you look at the inside cover of that book, the first page, it lists the supporters of the book. Do you see that?
A Yes.
Q It lists a number of supporters, correct?
A Yes.
Q It lists Purdue Pharma, LP, correct?
A Yes.
Q It lists, for example, Cephalon, Inc., correct?
A Yes.

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Q Endo Pharmaceuticals, right?
A Yes.
Q The American Academy of Pain Medicine?
A Yes.
Q And the American Pain Foundation, correct?
A Yes.
Q And in this book it discussed -- the parts you read, it discussed the concept of pseudoaddiction, right?
A The part you pointed out, yes.
Q And the behaviors associated with it?
A Yes.
Q It is not a true statement to say that most patients who use opioids for more than a year will not become addicted, is it?
MR. LIFLAND: Object to the form of the question.
Q (BY MR. PATE) That's an overbroad statement, isn't it?
A Is it not -- please rephrase the question. Go on.
Q It's wrong to say that most patients who use opioids for more than a year will not become addicted, isn't it?
MR. LIFLAND: Object to the form of the

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question.
A Patients who use opioids for more than a year who are under the appropriate care of a physician and understand the risks and benefits and they're monitored carefully by the physician, most patients won't become addicted.
Q (BY MR. PATE) So you think that's a true statement?
A Given the caveats I just spoke about, yes.
Q But the statement I said is broader than that. That's what I'm asking you. Just do you agree that most patients who use opioids for more than a year will not become addicted? Just that alone.
A I don't know the data for that.
Q You don't know the data supporting such a broad statement, correct?
A Correct.
Q Janssen doesn't have data supporting such a broad statement, correct?
A Other than from our own clinical trials where we treated patients for more than a year and had follow-up data with adverse event reporting.
Q But those clinical studies wouldn't support the broad statement that most patients

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taking any opioid for more than a year will not become addicted, correct?
A Those studies couldn't necessarily be broadened to include all opioids.
Q They could not?
A Nor could -- no, especially because they wouldn't know what the follow-up was for those patients. We know what the follow-up is for our studies.
Q When you are presenting a study, it's important to present and explain the limitations of that study, right?
A Yes.
Q You have to explain the context in which the study was conducted, right?
A The methodology, the patient population, the interventions and, therefore, the limitations in the data.
Q You should not report the good things out of a study without the bad things, right?
A We're reporting the findings of the study regardless of whether they're good or bad.
Q Right. You need to report the findings of the study in the context in which that study was done, right?

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A Yes.
Q So that people can understand what's the significance of this study, right?
A Yes.
Q So that they don't exaggerate or take out of context what a study means, right?
A So that we understand the limitations of the study.
Q And that's important to do when you're presenting research, isn't it?
A To give the context of what the clinical trial or what the study looked at and the limitations, yes.
Q When you're providing information about opioids to doctors, it's important to include the limitations of any study you're providing them, right?
A In the context of what were the -- what was the methodology, what was the patient population, how did we assess the patients so they understand where the limitations are, and we bring that to fore also, yes.
Q You shouldn't describe just the conclusion without the context and the limitations of the study, correct?

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A Unless there are other studies that support a broader context, but within a specific study, yes.
(Exhibit 16 marked for identification.)
Q (BY MR. PATE) I've handed you what we've marked as Exhibit 16. Do you recognize that?
A I don't.
Q Exhibit 16 is an email among some J&J employees dated August 1, 2008, correct?
A Correct.
Q Regarding a tapentadol newsletter, correct?
A Correct.
Q Tapentadol is Nucynta?
A Yes.
Q An opioid?
A Yes.
Q The newsletter itself is included in Exhibit 16 dated August of 2008. Do you see that?
A I do.
Q On the second page underneath the heading "Undertreatment of Pain" --
A Yes.
Q -- it says near the bottom of the paragraph, "Despite these developments, recent

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studies and reports suggest that many types of pain in patient populations are undertreated."

Do you see that?

A I do.

Q This is in 2008, correct?

A Yes.

Q This is after the prescribing of opioids has increased significantly from the mid '90s, correct?

A Increased significantly, yes.

Q And it says that, "It's still the case that there are many types of pain in patients who are undertreated for pain." Right?

A Yes.

Q It provides a reference to a 2001 article from the National Pharmaceutical Council for that, doesn't it?

A Yes.

Q Is a 2001 article indicative of how things exist in 2008?

A I can't say that anything changed, but I would have quoted a later source.

Q Well, you have agreed that certain things have changed between the mid '90s and 2008, haven't you?

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A That the prescription of opioids increased, yes.

Q Significantly?

A Yes.

Q And yet this is relying on a 2001 source to tell people the state of pain treatment in the country in 2008, correct?

A That's what it appears to be, yes.

Q A 2001 source does not provide any information or data about how things exist as of 2008, does it?

A This is not a final document. So I don't know what was put out into the public.

Q Would you be able to find that out?

A I don't know.

Q This is not one of the documents that you brought with you today?

A It is not.

Q You agree that you should not cite a 2001 paper as evidence of how things exist in 2008, correct?

A I would agree that if we can find later citations, they would be appropriate.

Q And you would agree that if that's the only citation that you have, you should disclose the limitations of that, correct?

A Unless there was some reason to believe that nothing has changed, I would agree with that.

Q Well, in that case, you would indicate why nothing had changed from 2001 to 2008, correct?

A Correct. Again, I don't know what was put out into the public.

Q Moving down the next sentence reads, "Additionally, data from a 1999 survey suggests that only one in four individuals with pain receives the appropriate treatment." Correct?

A Correct.

Q And it's referring to the same survey, right?

A Yes.

Q Again, data from 1999 doesn't indicate the number of individuals receiving appropriate treatment for pain in 2008, does it?

A I would look for a later citation.

Q Because a lot of things can change between 1999 and 2008, can't they?

A Hopefully there would be more data, yes.

Q A lot of things we know now did change between 1999 and 2008 with respect to pain treatment, right?

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MR. LIFLAND: Object to the form of the question.

A If you go back to what you stated, that there was a significant increase in the number of prescriptions for opioids, yes, that's correct.

Q (BY MR. PATE) 2008 was getting closer and closer to the height of opioid prescribing in this country, wasn't it?

A If you're talking about -- I don't recall the year that was the height of opioid prescribing, but it was around that time to my knowledge, yes.

Q You previously testified that there is still a need for more research in the area of addiction risk for chronic opioid treatment, correct?

MR. LIFLAND: Object to the form of the question.

A There's always a need for good and better research. I would agree with that.

Q (BY MR. PATE) That's sitting here today, right? In 2018 that's your view?

A I haven't been significantly involved since 2011, but there are still issues around pain management and treatment that would require more investigation.

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Q I just want to be clear. You're testifying based on how you feel today, right?
A Relative to? I'm sorry.
Q You're saying that there's more research that could or should be done about the addiction rate of opioids. I'm saying that's your view today. You're not stating that as of 2008 or as of 2007.
You're saying, as we sit here today, you believe there's more research that needs to be done about the addiction rate --
A Addiction rate, okay.
Q -- of long-term chronic opioid treatment?
MR. LIFLAND: Object to the form of the question.
A I think it would be useful to do more long-term therapy. I think that there have been a number of articles and review articles, including the Cochrane review, that summarize a lot of the information, and the fact that they're internally consistent is reassuring.
That doesn't mean that having more long-term data wouldn't be useful, particularly around long-term opioid use.
Q (BY MR. PATE) And the addiction rate of that long-term opioid use, right?

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A And the addiction rate of that long-term opioid use.
Q And the long-term benefits to patients who are on those drugs for more than three months, right?
A Yes. As I stated, there are some reports of longer termed therapy that goes out to two years certainly on our part, but we can always use more data in a broader sense on long-term therapy with opioids.
Q And you would like to see more data about that?
A Yes, I would.
Q And the CDC, you're aware that they feel the same way, right?
A Yes.
Q They've stated that there needs to be more research about this, right?
A Yes.
Q Better research about it?
A Yes.
Q More applicable research about it?
MR. LIFLAND: Object to the form of the question.
A Could you define "applicable."

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Q (BY MR. PATE) For how those drugs are being used long term?
A Yes.
Q But we do know that from 1996 for a number of years that opioid prescriptions increased, correct?
A Yes.
Q And we know that currently, sitting here today, we are in the middle of an opioid epidemic, correct?
MR. LIFLAND: Object to the form of the question.
A That the incidence of opioid abuse and the attendant outcomes for that have increased, yes.
Q (BY MR. PATE) It's a crisis, correct?
A It's been termed a crisis.
Q It wasn't a crisis in 1996, was it?
A I don't recall that it was termed a crisis.
Q And opioid prescribing has increased since then, right?
A Yes.
Q And now it's a crisis. Now there's an opioid crisis, right?
MR. LIFLAND: Object to the form of the

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question.
A You're making a cause and effect there.
Q (BY MR. PATE) No. I'm just asking a question.
A All right. I just want to clarify that. It's been termed a crisis, yes.
Q Sitting here today, Janssen is not doing anything to pay for research to be done related to opioid addiction risks, is it?
MR. LIFLAND: Object to the form of the question.
A I'm not aware of any ongoing studies or supported studies.
Q (BY MR. PATE) Janssen isn't funding anyone else to do any opioid addiction studies right now?
MR. LIFLAND: Object to the form of the question and also beyond the scope. You can answer based on your personal knowledge.
A I'm not aware.
Q (BY MR. PATE) Janssen isn't currently doing any research about the risks or benefits of opioids, is it?
MR. LIFLAND: Same objections.
A About the risks or benefits of opioids.

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Well, as part of the risk -- the REMS program, we are supporting surveillance programs on our opioids. So that would be studies that look at risks and -- well, certainly the risks associated with it. So we do support the ongoing risk evaluations work that the FDA mandates.

Q (BY MR. PATE) For what opioids?

A Right now we have it for Duragesic.

Q Any others?

A No.

Q What research existed in 1996 about the addiction rate for opioids for chronic pain?

A I'm not aware of the literature for chronic pain in general. I'm not aware of the literature. I'm just not familiar with it.

Q Are you aware of any literature that existed in 1996 about what the risk of addiction was for someone who was on long-term opioid treatment for more than three months?

A For more than three months. I don't recall, no.

Q In 1997?

A I don't recall, no.

Q In 1998?

A For that period of time till we did our

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own studies just looking within our own studies of long-term use of Duragesic.

Then the reports that came out including the Cochrane, I'd have to go back to each individual report to see what the length of treatment was.

Q The earliest report out of those four you cited, the Fleming, the Boscarino and all those, the earliest one was in 2007, wasn't it?

A I don't recall the dates, but I'll accept that.

Q Between 1996 and now, there is more data or let's just say information available to us about what happens when more people start taking opioids, isn't there?

MR. LIFLAND: Object to the form of the question.

A What happens when -- I'm not following you. You mean outcomes?

Q (BY MR. PATE) Yes.

A There have been more data generated. We generated some data with our own compounds. So, yes.

Q As time goes on?

A There's been more data generated.

Q And as time goes on, we learn new things,

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right?

A Yes.

Q More things happen, right?

A Yes.

Q We gather more information?

A Yes. So, yeah, our knowledge increased from 1996 and on.

Q Right. And one of the things that has happened from 1996 till now is there's been more opioid prescriptions, right?

A Yes.

Q And there's also, we all know, been more opioid deaths, right?

A Yes.

MR. LIFLAND: Object to the form of the question.

Q (BY MR. PATE) And there's been more --

A Again, so you're not making cause and effect?

Q Has there been more opioid deaths between 1996 and now, has that increased?

A Yes.

Q Have the number of people addicted to opioids increased between now -- from 1996 to now?

A That's my understanding, yes.

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(Exhibit 17 marked for identification.)

Q (BY MR. PATE) I've handed you a document marked as Exhibit 17. Do you recognize those?

A I do.

Q Those are the CDC guidelines for prescribing opioids for chronic pain, correct?

A Yes.

Q Put out in 2016; is that right?

A Yes.

Q Is there anything that Janssen disagrees with in the CDC guidelines?

MR. LIFLAND: Object to the form of the question.

A I'm not aware of what Janssen's focus -- how Janssen feels about the CDC guidelines. I can't speak to that.

Q (BY MR. PATE) Has Janssen done any research to determine whether or not any of the conclusions reached in the guidelines are correct?

A Not to my knowledge.

Q Has Janssen done -- excuse me. Has Janssen done any research indicating that what the CDC says in here is wrong?

A Not to my knowledge.

Q Are you aware of any studies that indicate

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that anything that the CDC says in here is wrong?
MR. LIFLAND: Object to the form of the question.
A I'm not.
Q (BY MR. PATE) Is Janssen currently doing any research related to the findings in the CDC guidelines?
MR. LIFLAND: Object to the form of the question.
A The work that Janssen is doing is currently the surveillance work that we are obligated to do under the REMS program for Duragesic. Whether that constitutes following the guidelines, I'm not sure. I'd have to go back to the guidelines that are in here.
I believe as part of the REMS there are also long-term studies that we're obligated to do, and I would assume that we would meet our regulatory obligations. But how that relates to the CDC guidelines, I don't know.
Q (BY MR. PATE) If you look on Page 2 of Exhibit 17 near the end of the first paragraph, it says, "However, few studies have been conducted to rigorously assess the long-term benefits..." Sorry, the end of the first paragraph.

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A Okay.
Q Top of the page. "However, few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain (pain lasting more than three months) with outcomes examined at least one year later."
Correct?
A Yes.
Q You agree with that, don't you?
A I don't disagree with that. We have our own studies that look at outcomes that go beyond a year.
Q Do you disagree with the statement that "Few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain for more than three months"?
A I'm not aware of any studies. Yes, I would agree with that.
Q This was published in 2016, correct?
A Yes.
Q If you'll turn to Page 7 underneath the heading "Summary of findings for clinical questions." Do you see that?
A I do.
Q There's a sentence that reads, "In

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summary, evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose dependent."
Did I read that correctly?
A Yes.
Q Do you agree with that statement?
A Overall, yes, we do need more long-term therapy -- we do need more data on long-term therapy of opioids.
Q Is Janssen doing any research or does it have any research that indicates that the CDC is wrong?
A No. We have data on our compounds that go beyond a year's time where patients continue to benefit, but that doesn't rise to the level of evidence that the CDC is addressing here.
Q Are you currently, Janssen, doing anything to obtain this type of evidence that the CDC says we need?
A Other than ongoing adverse event reporting for Duragesic on patients who are on Duragesic, especially long-term, and I'd have to go back and

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see what our regulatory obligations are under the REMS program.
Q You are required to do those things under the REMS program, correct?
A Correct.
Q You are required to report those adverse events, correct?
A Correct.
Q Is there anything that Janssen is voluntarily doing in order to find the evidence that the CDC says we need here about long-term opioid treatment?
MR. LIFLAND: Object to the form of the question.
A Much of the information that is now a regulatory requirement was done voluntarily by Janssen and then it became a regulatory requirement.
So I just want to be clear that much of the surveillance that we had in place was voluntary on the part of Janssen, and because it monitored for issues of abuse, misuse, diversion and was considered to be good data, it became more widely required.
Q (BY MR. PATE) That wasn't really my question.

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My question was: Is there anything that Janssen is voluntarily doing right now in order to try to find evidence that the CDC says we need in these guidelines?

MR. LIFLAND: Object to the form of the question; beyond the scope of the designated topics.

You can answer if you know in your personal capacity.

A I don't know.

Q (BY MR. PATE) It's not beyond the scope. The topics are about research that J&J is doing, about opioid risks and benefits. I'm asking you what research you're doing.

CDC says we need research. I'm asking if right now -- all I'm asking is right now is J&J doing the research that the CDC says we need?

MR. LIFLAND: Same objections.

A And what I'm saying is that we are doing research into long-term use, and there are studies that the FDA has mandated. You specifically said "voluntary." I'm not aware of any.

Q (BY MR. PATE) The ones you're doing are the ones you're required to do under the REMS program, right?

A That's correct.

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Q What are they?

A They're long-term -- well, long-term, the surveillance programs that are underway that look at issues of abuse, misuse and diversion, and there are long-term treatment protocols that look at issues of hyperalgesia, I believe.

Q What is J&J's role with respect to those surveillance programs?

A We support -- there's now an independent group that conducts that surveillance, and we support the group that does the surveillance.

Q When you say support, you give them money?

A Correct.

Q And you report adverse events that are reported to you?

A Correct.

Q Anything else?

A That's what I'm aware of.

Q Have you put any of your own doctors or scientists on this project?

A Other than to do the mandated long-term studies under the REMS?

Q I thought you said a third party was doing that now.

A That's the surveillance part of it.

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Q Okay.

A There are required studies that we need to do with our compounds, and that would fall under our mandate because it's Duragesic specific.

Q Okay. So there are studies separate from the surveillance programs --

A Correct.

Q -- that Janssen is currently required to do about Duragesic?

A Under the REMS program, yes.

Q What are those studies?

A I believe that's the study of hyperalgesia. I'd have to confirm that.

Q What is hyperalgesia?

A It's one of the long-term potentials for patients who are on opioids to increasingly get less benefit from the opioid because of this issue of hyperalgesia. The benefit is lost and, in fact, increasing the dose may worsen the problem.

Q For someone who is on opioids for an extended duration?

A Yes.

Q When is that study going to conclude?

A I don't know.

Q What stage is it in currently?

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A I don't know.

Q How much money has J&J spent on it?

A I don't know.

Q How much money has J&J spent on any research related to the addiction risk associated with long-term opioid therapy?

A Other than the ongoing surveillance right now that we support?

Q No, total.

MR. LIFLAND: Object to the form of the question.

A I don't know.

MR. LIFLAND: I think we withdrew this topic.

Q (BY MR. PATE) Other than the surveillance program and the required studies under the REMS, is there anything that J&J is currently doing to try to gather the evidence that the CDC says we need about long-term opioid treatment?

MR. LIFLAND: Object to the form of the question.

A Not with our drugs and not with any other drugs.

Q (BY MR. PATE) Not with any opioids, right?

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A Not that I'm aware of.
Q J&J has a lot of doctors that work there, right?
A There are quite a number. A lot. I think a lot is a reasonable, a reasonable assessment.
Q J&J is a big pharmaceutical company, isn't it?
A Yes.
Q It's one of the largest in the country, correct?
A Correct.
Q You have a lot of very smart people who work for you, don't you?
A I certainly hope so.
Q A lot of very smart scientists, right?
A Yes.
Q A lot of very smart doctors, right?
A Yes.
Q A lot of very smart researchers, right?
A Yes.
Q A lot of people capable of performing studies about the effects of drugs, right?
A And are doing that about the effects of our drugs, yes.
Q You have a lot of resources at your

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disposal, don't you?
A I can't speak to the resources in any particular area. Resources are allocated.
Q You're a $300 billion company, aren't you?
MR. LIFLAND: Object to the form of the question.
A I don't know.
Q (BY MR. PATE) Right now, absent what is being required to do, J&J is not using any of those smart people or any of those resources in order to determine and investigate what the long-term benefits and risks of opioids are, is it?
MR. LIFLAND: Object to the form of the question.
A We are not conducting studies or research other than what's mandated under the REMS program and surveillance to look at that question, no.
Q (BY MR. PATE) Do you think that J&J should do that?
MR. LIFLAND: Object to the form of the question.
A You're asking a personal opinion on that?
Q (BY MR. PATE) Sure.
A Well, I think over the course of the marketing for Duragesic and tapentadol, our

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surveillance data consistently showed for our compounds, Duragesic and Nucynta tapentadol, rates of use, misuse and diversion were consistently low and lower than most other long-acting opioids that were on the market. I think we were comfortable knowing that the steps that we took helped to minimize use, misuse and diversion of our compounds.
I think in any field you can argue that more research is needed, and that it's up to the company to make a determination of how best to allocate its resources to determine where more research is going to be supported.
Q J&J has so far right now, as far as you know, determined not to allocate any more resources to opioids, right?
A Beyond --
MR. LIFLAND: Object to the form of the question.
A Beyond the studies that are required and the surveillance programs for our products, correct.
Q (BY MR. PATE) J&J is no longer making any opioids other than Duragesic; is that right?
A I believe we're still making Tylenol with codeine.
Q Schedule II opioids.

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A Okay. No.
Q You sold off Nucynta a couple years ago, right?
A Correct.
Q Duragesic has been off patent for a number of years, right?
A Since 2005.
Q So there's no product, opioid product, that J&J, other than Duragesic, that J&J currently has on the market, right?
A Schedule II.
Q And it's not allocating any resources related to the risks and benefits of Schedule II opioids, is it?
A Aside from the mandated REMS studies and surveillance programs.
Q J&J is not doing the research itself. It's also not providing the funding to anyone else to do that research right now, is it?
MR. LIFLAND: Object to the form of the question.
A Other than the mandated surveillance programs, yes.
Q (BY MR. PATE) Correct?
A Correct.

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Q Are all the clinical trials that J&J has done with respect to its opioids listed on one of your documents?
A I believe so, yes.
Q Can you point me to that document, please.
A We -- at a very high level we certainly speak of the periodic safety update reports, and all of the studies are in the periodic safety update reports, and we have some examples of those.
Q What are you looking at?
A I'm just aware that we report all of the studies in the periodic safety update reports and we have some.
Then beyond that, we break out the specific types of studies and the studies that fit under that specific type.
But if you're talking about the studies that go back to the preclinical work, the pharmacokinetic studies, I don't believe we have those specifically listed here.
Q Are the clinical studies that you do have listed, are those listed in Exhibit 3?
I tell you what, why don't we do it this way. Will you hand me the stack of the high level documents that you brought with you today that we

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haven't marked yet.
MR. LIFLAND: I think we gave you the whole stack. Do you want his copy of it?
MR. PATE: I want to mark it.
MR. LIFLAND: Yeah.
THE WITNESS: These two.
(Exhibit 18 marked for identification.)
Q (BY MR. PATE) I'm going to hand you what I've marked as Exhibit 18 which is the timeline.
A Uh-huh.
Q Can you identify that for me.
A This is the timeline for key events around Duragesic and Nucynta and Nucynta ER.
Q Did you make this timeline?
A I was aware of some of the dates on here. I provided some of the dates, but the timeline was developed by counsel.
(Exhibit 19 marked for identification.)
Q (BY MR. PATE) You've been handed a document marked as Exhibit 19. What's that one?
A "Selected studies, research and analysis supporting certain categories of statements."
Q Did you put that together?
A Again, I had input to it. Many of the studies were done while I was at the company, but

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the document itself was developed by counsel.
Q Who determined the categories of statements that you would include support for?
A That was collective. These were major categories that we felt that the studies fell under. So, for example, we were aware of the need for safety studies longer than 90 days. So we looked at those specifically.
(Exhibit 20 marked for identification.)
Q (BY MR. PATE) You've been handed a document marked as Exhibit 20. Do you know what that one is?
A "Sources of knowledge regarding abuse, misuse, dependence or addiction."
Q Is it J&J's sources of knowledge regarding those things?
A Yes.
(Exhibit 21 marked for identification.)
Q (BY MR. PATE) You've been handed a document marked Exhibit 21. Can you identify that one, please.
A "Let's Talk Pain References."
Q What is that?
A These are references with respect to the monograph we spoke about, "Let's Talk Pain."

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(Exhibit 22 marked for identification.)
Q (BY MR. PATE) The next document you've been handed is Exhibit 22. Do you recognize that one?
A The "Index to Duragesic Risk Management Plans."
Q What is that?
A In the course of our marketing with Duragesic, we had an obligation at times to provide activities that fell under the rubric of risk management, and these were the plans that we filed periodically with the FDA with the data for our drug, in this case, Duragesic.
It relates to the internal surveillance and to the external surveillance that we had, that we put in place for Duragesic.
(Exhibit 23 marked for identification.)
Q (BY MR. PATE) You've been handed a document marked as Exhibit 23. Can you identify that one?
A Nucynta IR, immediate release, and ER, extended release, safety surveillance plans.
Q What are those?
A Similar to what we just discussed for Duragesic. These were the surveillance programs

that we reported to the -- we had in place and reported to the FDA periodically on the findings from these streams of data.

(Exhibit 24 marked for identification.)

Q (BY MR. PATE) The next one has been marked as Exhibit 24. What's that?

A "Opioids manufactured, owned and/or developed by Janssen since 1996."

Q So this relates to Topic No. 35?

A Correct.

Q I have one that I don't see from you that is prescriberesponsibly.com references. Has that already been marked?

A No.

(Exhibit 25 marked for identification.)

Q (BY MR. PATE) That one has been marked as Exhibit 25. Can you tell me what that is?

A References that refer to tab references for articles that were used in the website prescriberesponsibly.com.

Q Those are all the ones you're aware of?

A Yes.

MR. PATE: It's 5:00. Why don't we take a break for the evening, and we'll pick back up in the morning.

MR. LIFLAND: Okay. Do you want to start at 8:00? We can go off the record.

VIDEOGRAPHER: Off the record at 4:58 p.m.

(DEPOSITION ADJOURNED AT 4:58 P.M.)

JURAT

State of Oklahoma vs. Purdue Pharma, et al.

I, BRUCE MOSKOVITZ, M.D., do hereby state under oath that I have read the above and foregoing deposition in its entirety and that the same is a full, true and correct transcription of my testimony so given at said time and place.

_____

Signature of Witness

Subscribed and sworn to before me, the undersigned Notary Public in and for the State of Oklahoma by said witness, BRUCE MOSKOVITZ, M.D., on this _____day of_____, 2019.

_____

NOTARY PUBLIC

MY COMMISSION EXPIRES:_____

(JMc) JOB FILE #135845

ERRATA SHEET

State of Oklahoma vs. Purdue Pharma, et al.

DEPOSITION OF BRUCE MOSKOVITZ, M.D.

REPORTED BY: Jane McConnell, CSR RPR RMR CRR

DATE DEPOSITION TAKEN: January 9, 2019

JOB FILE NO. 135845

PAGE	LINE	IS	SHOULD BE

C E R T I F I C A T E

I, Jane McConnell, Certified Shorthand Reporter, do hereby certify that the above-named BRUCE MOSKOVITZ, M.D., was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth, in the case aforesaid; that the above and foregoing deposition was by me taken in shorthand and thereafter transcribed; and that I am not an attorney for nor relative of any of said parties or otherwise interested in the event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 11th day of January, 2019.

Jane M. McConnell

Jane McConnell, CSR RPR RMR CRR